FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: A-200SL-OR3-C

Product name(s): LEPTOSAR 200 SL

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 23/02/2021

MS Finalisation date: 01/07/2022

Version history

When	What
February 2021	First submission for product authorization to zonal RMS.
May 2021	Dossier sent for evaluation
December 2021	zRMS finalised evaluation
July 2022	Final version prepared by zRMS after Commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The text of the applicant was not rewritten. The zRMS' text is on grey background.

7.1.1 Critical GAPs and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation LEPTOSAR 200 SL are presented in Table 7.1-1. The applicant relies on his own data and the DAR data. The applicant submitted new residue data on oilseed rape (4 trials), maize (4 trials) and wheat (4 trials). New trials were consistent with the intended GAP, conducted according to the worst-case scenario and presented "no residue situation" (< LOQ (0,01)). Therefore, they are sufficient for the evaluation of the intended uses except fruits, nuts and Solanaceae (G). The unprotected data supporting pome and stone fruits, nuts as well as Solanaceae were taken by the applicant from acetamiprid DAR (2001) and were acceptable.
For clarity purposes the extensive GAP table (Table 7.1-1) was finalized below in a simplified form (CEU, LEPTOSAR 200 SL, foliar spray); the extrapolations triggering the BBCH update were marked with an asterisk; on dark-grey background items grown for seeds and not for consumption or feeding are presented:

	Crop	F, G	Application			Application rate per treatment			PHI
			BBCH	number	interval	kg as/hL	water L/ha	kg as/ha	
1-5	Winter oilseed rape	F	17-71	1	n.a.	0.015 – 0.030	200-400	0.060	F
41-45	Spring oilseed rape, white and black mustard, Chinese mustard, turnip rape	F	20-71	1	n.a.	0.015 – 0.030	200-400	0.060	F
6, 56	Maize, popcorn, sorghum, proso millet **	F	51-75	1	n.a.	0.012 - 0.02	300-500	0.060	F
59-61	Spring wheat, Winter wheat Winter triticale Winter rye	F	30-59	1	n.a.	0.01 – 0.02	200-400	0.040	F
57-58	Spring rye Durum, Spelt, einkorn wheat, emmer wheat	F	30-65	1	n.a.	0.01 – 0.02	200-400	0.040	F
63-89	Wild apple, Pear, Chinese pear, Quince, medlar, plum	F	11-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.050	14
	Sour and sweet cherry, peach, nectarine apricot	F	11-65*	1 - 2	7-14	0.0033 – 0.025	200-750	0.050	14
90-91	Hazelnut, Walnut	F	before 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.050	14
62	Tomato, aubergines, pepper	G	20 –89	1	n.a.	0.008 – 0.02	300-750	0.060	3
54	Sunflower	F	10-65	1	n.a.	0.012 - 0.02	300-500	0.060	F
46-47	Flax	F	10-61	1	n.a.	0.015 – 0.030	200-400	0.060	F
48-50	Hemp	F	11-59	1	n.a.	0.015 – 0.030	200-400	0.060	F
51-52	Soybean	F	11-65	1	n.a.	0.012 - 0.03	200-500	0.060	F
53	Poppy seed	F	10-39	1	n.a.	0.0075–0.015	200-400	0.030	F
55	Pumpkin seed	F	21-65*	1	n.a.	0.012 - 0.03	200-500	0.060	F
92	Tobacco	F	11–85	1 - 2	7-10	0.0033–0.025	200-750	0.050	n.a.
93	Common osier, purple willow	F	11-69	1 - 2	10	0.0033-0.025	200-750	0.050	n.a.

94	Forest, ornamental nurseries, restockings, afforestations, forest trees' seed plantations; Christmas trees	F	11-69	1	n.a.	0.0125-0.025	200-400	0.050	n.a.

Extrapolations:
1. ** Sweet corn i.e. Zea mays L. saccharata Koern ("sugar maize" according to the applicant) cannot be extrapolated from the residue data of the submitted maize trials as a harvest (NCH) in the trials was performed at BBCH ~ 89. Sweet corn is extrapolable only from immature maize i.e. maize harvested at BBCH stage 75, and in any case before BBCH stage 85 (SANCO 7525/VI/95 Rev. 10.3). Thus, the use in sweet corn cannot be approved.
2. * according to SANCO 7525/VI/95 Rev. 10.3 extrapolations were permissible only for treatments before the edible parts are formed i.e. BBCH 65.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for acetamiprid as they are presented in the table below
~~0.4 mg/kg in oilseed rape, white mustard, black mustard, Chinese mustard, turnip rape, flax, common hemp, soybean, poppy seeds, sunflower, pumpkin seeds, 0.01 mg/kg in maize, sugar maize, Popcorn, sorghum, proso true millet, 0.1 mg/kg in spring/winter wheat, triticale, durum wheat, spelt wheat, einkorn wheat, emmer wheat, 0.05 mg/kg in spring/winter barley, 0.01 mg/kg in spring/winter rye, 0.4 mg/kg in wild apple, pear, Chinese pear, 0.8 mg/kg in quinces, medlar and apricots, 1.5 mg/kg in sweet and sour cherries, 0.5 mg/kg in tomatoes, 0.3 mg/kg in paprika, 0.2 mg/kg in aubergines, peaches and nectarines, 0.03 mg/kg in plums, 0.07 mg/kg in hazelnuts and walnuts~~

Code number	**Groups and examples of individual products to which the MRLs apply**	**Acetamiprid Reg. (EU) 2019/88**
0120060	Hazelnuts/cobnuts	0,07
0120110	Walnuts	0,07
0130010	Apples	0,4
0130020	Pears	0,4
0130030	Quinces	0,8
0130040	Medlars	0,8
0140010	Apricots	0,8
0140020	Cherries (sweet)	1,5
0140030	Peaches	0,2
0140040	Plums	0,03
0231010	Tomatoes	0,5
0231020	Sweet peppers/bell peppers	0,3
0231030	Aubergines/eggplants	0,2
0234000	Sweet corn	0.01*
0401010	Linseeds	0.01*
0401030	Poppy seeds	0.01*
0401050	Sunflower seeds	0.01*
0401060	Rapeseeds/canola seeds	0,4
0401070	Soyabeans	0.01*
0401080	Mustard seeds	0.01*
0401100	Pumpkin seeds	0.01*
0401140	Hemp seeds	0.01*
0500030	Maize/corn	0.01*
0500040	Common millet/proso millet	0.01*
0500070	Rye	0.01*
0500080	Sorghum	0.01*

0500090	Wheat	0,1

as laid down in Reg. (EU) 396/2005 are not expected.

The chronic and the short-term intakes of acetamiprid residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses except sweet corn.

To prevent formation of metabolite IM-1-5 after application of product contained acetamiprid it is proposed to add to the label following precautions: “Do not apply on calcareous soils (pH > 7)”.

Data gaps

Noticed data gaps are none.

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Winter oilseed rape (BRSNW)	N-EU	A-200SL-OR3-C	F	Pollen Beetles (Meligethes aeneus) – MELIAE	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	1	n.a.	0.015 – 0.030	200-400	0.060	F	
2	Winter oilseed rape (BRSNW)	N-EU	A-200SL-OR3-C	F	Rape stem weevil (*Ceutorhynchus napi*) - CEUTNA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 17-59	1	n.a.	0.015 – 0.030	200-400	0.060	F	
3	Winter oilseed rape (BRSNW)	N-EU	A-200SL-OR3-C	F	Cabbage stem weevils (*Ceutorhynchus pallidactylus*) – CEUTQU	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 17-59	1	n.a.	0.015 – 0.030	200-400	0.060	F	
4	Winter oilseed rape (BRSNW)	N-EU	A-200SL-OR3-C	F	Cabbage seed weevil (*Ceutorhynchus obstrictus*) – CEUTAS	SL	200 g/L	Foliar spray	After reaching thresholds or	1	n.a.	0.015 – 0.030	200-400	0.060	F	

									after warning service appeal BBCH 59-71							
5	Winter oilseed rape (BRSNW)	N-EU	A-200SL-OR3-C	F	Brassica pod midge (*Dasineura brassicae*,) - DASYBR	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	1	n.a.	0.015 – 0.030	200-400	0.060	F	
6	Maize (ZEMAX)	N-EU	A-200SL-OR3-C	F	European corn borer (*Ostrinia nubilalis*) - PYRUNU	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	1	n.a.	0.012 - 0.02	300-500	0.060	F	
41	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	N-EU	A-200SL-OR3-C	F	Pollen beetles (*Meligethes aeneus*) – MELIAE	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	1	n.a.	0.015 – 0.030	200-400	0.060	F	
42	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU)	N-EU	A-200SL-OR3-C	F	Rape stem weevil (*Ceutorhynchus napi*) - CEUTNA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	1	n.a.	0.015 – 0.030	200-400	0.060	F	

	turnip rape (BRSRO)															
43	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	N-EU	A-200SL-OR3-C	F	Cabbage stem weevils (*Ceutorhynchus pallidactylus*) – CEUTQU	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	1	n.a.	0.015 – 0.030	200-400	0.060	F	
44	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	N-EU	A-200SL-OR3-C	F	Cabbage seed weevil (*Ceutorhynchus obstrictus*) – CEUTAS	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	1	n.a.	0.015 – 0.030	200-400	0.060	F	
45	Spring oilseed rape (BRSNS); white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU); turnip rape (BRSRO)	N-EU	A-200SL-OR3-C	F	Brassica pod midge (*Dasineura brassicae,*) - DASYBR	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	1	n.a.	0.015 – 0.030	200-400	0.060	F	
46	Flax (LIUUT) - seeds and fiber production	N-EU	A-200SL-OR3-C	F	Large flax flea beetle (*Aphthona euphorbiae*) - APHTEU; Small flax flea beetle (*Longitarsus parvulus*) - LONIPA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal	1	n.a.	0.015 – 0.030	200-400	0.060	F	

									BBCH 10-14							
47	Flax (LIUUT) - seeds and fiber production	N-EU	A-200SL-OR3-C	F	Cabbage thrips (*Thrips angusticeps*) - THRIAN; Flax thrips (*Thrips lini)* - THRILI	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-61	1	n.a.	0.015 – 0.030	200-400	0.060	F	
48	Common hemp (CNISA**)** - seeds and fiber production	N-EU	A-200SL-OR3-C	F	Hemp flea beetle (*Psylliodes attenuata*) - PSYIAT	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-14	1	n.a.	0.015 – 0.030	200-400	0.060	F	
49	Common hemp (CNISA**)** - seeds and fiber production	N-EU	A-200SL-OR3-C	F	European maize borer (*Ostrinia nubilalis*) - PYRUNU	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal (June)	1	n.a.	0.015 – 0.030	200-400	0.060	F	
50	Common hemp (CNISA**)** - seeds and fiber production	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP; Thrips (*Thysanoptera*) - 1THYSO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 39-59	1	n.a.	0.015 – 0.030	200-400	0.060	F	
51	Soybean (GLXMA) – seeds production	N-EU	A-200SL-OR3-C	F	Sitona (*Sitona sp.*) - SITNSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning	1	n.a.	0.012 - 0.03	200-500	0.060	F	

									service appeal BBCH 11-19							
52	Soybean (GLXMA) – seeds production	N-EU	A-200SL-OR3-C	F	Bishop bug (*Lygus rugulipennis*) – LYGURU; Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 61-65	1	n.a.	0.012 - 0.03	200-500	0.060	F	
53	Opium poppy (PAPSO) – seeds production	N-EU	A-200SL-OR3-C	F	Capsule midge (*Dasineura papaveris*) -DASYPA; Capsule weevils (*Neoglocianus maculaalba*) - CEUTMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-39	1	n.a.	0.0075 – 0.015	200-400	0.030	F	
54	Sunflower (HELAN) – seeds production	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP; Lygus bug (*Lygus sp.*) - LYGUSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-65	1	n.a.	0.012 - 0.02	300-500	0.060	F	
55	Pumpkin (CUUPE) – seeds production	N-EU	A-200SL-OR3-C	F	Lygus bug (*Lygus sp.*) - LYGUSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 21-~~69~~ 65	1	n.a.	0.012 - 0.03	200-500	0.060	F	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)

56	~~sugar maize Zea mays L. convar. saccharata Koern. (ZEAMS);~~ Popcorn (ZEAME); sorghum (SORVU), proso true millet (PANMI)	N-EU	A-200SL-OR3-C	F	European corn borer *(Ostrinia nubilalis)* - PYRUNU; Aphids (*Aphididae*) – APXXSP;	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	1	n.a.	0.012 - 0.02	300-500	0.060	F	Sweet corn can be extrapolated only from maize harvested at BBCH stage 75, and in any case before BBCH stage 85 (SANCO 7525/VI/95 Rev. 10.3)
57	Spring rye (SECCS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	N-EU	A-200SL-OR3-C	F	Cereal leaf beetle (*Oulema melanopus*) – LEMAME	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 37-65	1	n.a.	0.01 – 0.02	200-400	0.040	F	
58	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	N-EU	A-200SL-OR3-C	F	Cereal bug (*Eurygaster maura*)- EURYMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	1	n.a.	0.01 – 0.02	200-400	0.040	F	
59	Spring wheat (TRZAS)	N-EU	A-200SL-OR3-C	F	Cereal bug (*Eurygaster maura*)- EURYMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal	1	n.a.	0.01 – 0.02	200-400	0.040	F	

									BBCH 30-59							
60	Winter wheat (TRZAW)	N-EU	A-200SL-OR3-C	F	Cereal bug (*Eurygaster maura*)-EURYMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	1	n.a.	0.01 – 0.02	200-400	0.040	F	
61	Winter triticale (TTLWI), Winter rye (SECCW)	N-EU	A-200SL-OR3-C	F	Cereal bug (*Eurygaster maura*)-EURYMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	1	n.a.	0.01 – 0.02	200-400	0.040	F	
62	tomato (LYPES), aubergine (SOLME), ~~Paprika~~ Pepper (CPSAN)	N-EU	A-200SL-OR3-C	G	Glasshouse whitefly(*Trialeurodes vaporariorum*) – TRIAVACommon cotton thrips (*Thrips tabaci*) – THRITB; Western grass thrips (*Frankliniella occidentalis*) - FRANOC; Leaf miner (*Phytomyza sp.)* - PHYYSP; Aphids (*Aphididae*) – APXXSP; , Lygus bug(*Lygus sp.)* - LYGUSP; Flea beetle (*Psylliodes*) - 1PSYIG	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20 – 89	1	n.a.	0.008 – 0.02	300-750	0.060	3	
63	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	

									BBCH 11-87						
64	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Codling moth (*Cydia pomonella*) - CARPPO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 69-74	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
65	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Pear leaf blister moth (*Leucoptera scitella*) - LEUCSC	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 57-69	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
66	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Apple fruit sawfly (*Hoplocampa testudinea*) - HOPLTE	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 65-69	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
67	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Apple leaf midge (*Dasineura mali*) - DASYMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
68	Wild apple (MABSY)	N-EU	A-200SL-OR3-C	F	Bracken clock (*Phyllopertha horticola*) - PHPHHO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	

69	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Aphids (Aphididae) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
70	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Codling moth (*Cydia pomonella*) - CARPPO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH-71-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
71	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Cherry slug sawfly(*Caliroa limacina*) - ERICLI	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
72	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Apple bud weevil(*Anthonomus piri*) - ANTHPY	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
73	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Pear leaf midge (*Dasineura pyri*) - DASYPY	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-79	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	

74	Pear (PYUCO), Chinese pear (PYUPY)	N-EU	A-200SL-OR3-C	F	Pear psylla (*Cacopsylla pyri*) - PSYLPI; Pear sucker (*Cacopsylla pyri-suga*) - PSYLPY; , Pear psyllid (*Cacopsylla pyricola*) - PSYLPC	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-71	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
75	Quince (CYDOB), medlar (MSPGE)	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
76	Quince (CYDOB), medlar (MSPGE)	N-EU	A-200SL-OR3-C	F	Codling moth (*Cydia pomonella*) - CARPPO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
~~**77**~~	~~Sour cherry (PRNCE), sweet cherry (PRNAV),~~	~~N-EU~~	~~A-200SL-OR3-C~~	~~F~~	~~Cherry fruit fly (*Rhagoletis cerasi*) - RHAGCE~~	~~SL~~	~~200 g/L~~	~~Foliar spray~~	~~After reaching thresholds or after warning service appeal BBCH 76-81~~	~~1 - 2~~	~~7-14~~	~~0.0033 – 0.025~~	~~200-750~~	~~0.025 - 0.050~~	~~14~~	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)
78	Sour cherry (PRNCE), sweet cherry (PRNAV),	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-~~87~~ 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)

~~**79**~~	~~Sour cherry (PRNCE), sweet cherry (PRNAV),~~	~~N-EU~~	~~A-200SL-OR3-C~~	~~F~~	~~Cherry slug sawfly (*Caliroa limacina*) - ERICLI~~	~~SL~~	~~200 g/L~~	~~Foliar spray~~	~~After reaching thresholds or after warning service appeal BBCH 71-87~~	~~1 - 2~~	~~7-14~~	~~0.0033 – 0.025~~	~~200-750~~	~~0.025 - 0.050~~	~~14~~	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)
80	Sour cherry (PRNCE), sweet cherry (PRNAV),	N-EU	A-200SL-OR3-C	F	Cherry fruit moth (*Argyresthia ephippiella*) - ARGYEP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
81	Sour cherry (PRNCE), sweet cherry (PRNAV),	N-EU	A-200SL-OR3-C	F	Cherry-stone weevil (*Anthonomus rectirostris*) - ANTHRE	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 57-~~69~~ 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)
82	Sour cherry (PRNCE), sweet cherry (PRNAV),	N-EU	A-200SL-OR3-C	F	Apple brown tortrix (*Pandemis heparana*) - PANDHE; Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller (*Archips rosana*) - CACORO; Whelk (*Tortricidae*) - 1TORTF; and other leaf caterpillars	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-~~87~~ 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)

83	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	N-EU	A-200SL-OR3-C	F	Apple brown tortrix (Pandemis heparana) - PANDHE; Reticulated tortrix (Adoxophyes orana) - CAPURE; European leaf roller (Archips rosana) - CACORO; Whelk (Tortricidae) - 1TORTF; and other leaf caterpillars	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-~~87~~ 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)
84	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-~~87~~ 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	No extrapolation beyond the BBCH 65 (SANCO 7525/VI/95 Rev. 10.3)
85	Plum (PRNDO)	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
86	Plum (PRNDO)	N-EU	A-200SL-OR3-C	F	Plum fruit sawfly (*Hoplocampa minuta*) - HOPLMI; Plum sawfly (*Hoplocampa flava*) - HOPLFL;	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 69-87	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
87	Plum (PRNDO)	N-EU	A-200SL-OR3-C	F	Plum fruit moth (*Laspeyresia funebrana*) - LASPFU	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service	1 - 2	14-21	0.0033 – 0.025	200-750	0.025 - 0.050	14	

									appeal BBCH 71-81							
88	Plum (PRNDO)	N-EU	A-200SL-OR3-C	F	European brown scale (*Parthenolecanium corni*) - LECACO	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 54-59	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
89	Plum (PRNDO)	N-EU	A-200SL-OR3-C	F	Apple brown tortrix (*Pandemis heparana*) - PANDHE; Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller (*Archips rosana*) - CACORO; Whelk (*Tortricidae*) - 1TORTF; and other leaf caterpillars	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87	1 - 2	7-10	0.0033 – 0.025	200-750	0.025 - 0.050	14	
90	Hazelnut (CYLAV)	N-EU	A-200SL-OR3-C	F	Aphids (Aphididae) – APXXSP; , Hazelnut weevil (*Curculio nucum*) - CURCNU; *(Oberea linearis)* - OBERLI; European brown scale (*Parthenolecanium corni*) - LECACO; , Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller (*Archips rosana*) - CACORO; other totrix and other leaf caterpillars	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11 – 65	1 - 2	7-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	

91	Walnut (IU-GRE)	N-EU	A-200SL-OR3-C	F	Aphids (Aphididae) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 50 – 65	1 - 2	10-14	0.0033 – 0.025	200-750	0.025 - 0.050	14	
92	Tobacco (NIOTA)	N-EU	A-200SL-OR3-C	F	Common cotton thrips (*Thrips tabaci*) - THRITB; Aphids (Aphididae) – APXXSP	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11 – 85	1 - 2	7-10	0.0033 – 0.025	200-750	0.025 - 0.050	n.a.	
93	Common osier (SAXVI) Purple willow (SAXPU)	N-EU	A-200SL-OR3-C	F	Aphids (Aphididae) – APXXSP, Balsam poplar leaf beetle (*Chrysomela populi*) - CHRSPO; (Chrysomela saliceti)- CHRSSA, Blue willow beetle (*Phratora vulgatissima*) - PHRRVU; Brassy willow leaf beetle (*Phratora vitellinae*) - PHRRVI; Cream-bordered green pea moth (*Earias clorana*) - EARICH; , Gall midge (*Dasineura marginemtorquens*) - RHABMA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-69	1 - 2	10	0.0033 – 0.025	200-750	0.025 - 0.050	n.a.	

94	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	N-EU	A-200SL-OR3-C	F	Aphids (*Aphididae*) – APXXSP, Springtails (*Collembola*) - 1COLLO; Larch case-bearer (*Coleophora laricella*) - COLELA	SL	200 g/L	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-69	1	n.a.	0.0125 - 0.025	200-400	0.050	n.a.	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation LEPTOSAR 200 SL is composed of acetamiprid.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of acetamiprid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Acetamiprid					
ADI	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610	2016	0.025 mg/kg bw per day	rat, developmental neurotoxicity study	100
ARfD	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610	2016	0.025 mg/kg bw	rat, developmental neurotoxicity study	100

7.1.2.1 Summary for acetamiprid

Table 7.1-3: Summary for acetamiprid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-5 7-11 13-17 19-23 27-31 34-38 41-45	Winter/ spring oilseed rape, white mustard, black mustard, Chinese mustard, turnip rape	Yes	Yes (4, < LOQ)	NR PHI covered by the time between the last application and harvest	Yes	Yes	No	No
6, 12, 18, 25-26, 32-33, 39-40, 56	Maize, ~~sugar maize~~ ~~Zea mays L. convar. saccharata Koern.,~~ Popcorn, sorghum, proso true millet	Yes	Yes (4, < LOQ)	NR PHI covered by the time between the last application and harvest	Yes	Yes		

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
24, 57-61	Cereals	Yes	Yes (4, < LOQ, extrapolate from wheat)	NR PHI covered by the time between the last application and harvest	Yes	Yes		
46-47	Flax	Yes	Yes (4, < LOQ, extrapolate from oilseed rape)	NR PHI covered by the time between the last application and harvest	Yes	Yes		
48-50	Common hemp							
51-52	Soybean							
53	Poppy seeds							
54	Sunflower seeds							
55	Pumpkin seeds							
62	Tomato	Yes	Yes (8)	Yes	Yes	Yes		
62	Aubergine	Yes	Yes (3 and extrapolated from tomato)	Yes	Yes	Yes		
62	~~Paprika~~ Pepper	Yes	Yes (5)	Yes	Yes	Yes		
63-68	Wild apple	Yes	Yes (14, extrapolate from apples)	Yes	Yes	Yes		
69-74	Pear, Chinese pear							
75-76	Qince, medlar							
77-82	Sour cherry, sweet cherry	Yes	Yes (4 and extrapolate from apples and plums)	Yes	Yes	Yes		
83-84	Peach, nectarine apricot	Yes	Yes (extrapolate from apples and plums)	Yes	Yes	Yes		
85-89	Plum	Yes	Yes (7)	Yes	Yes	Yes		
90	Hazelnut	Yes	Yes (extrapolate from apples and plums)	Yes	Yes	Yes		
91	Walnut							

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
92	Tobacco	NR						
93	Common osier, Purple willow							
94	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

According to EFSA Journal 2021;19(9):6830 the metabolism of acetamiprid following foliar applications was investigated in crops belonging to the groups of fruit crops, root crops, leafy crops and pulses/oilseeds indicating acetamiprid as the main metabolite in primary crops. Studies investigating the effect of processing on the nature of acetamiprid (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residue identified in metabolism studies was the metabolite IM-1-5, the presence of which was not confirmed in the rotational crop field studies. It is also expected that residues in floral nectar resulting from the use of acetamiprid in primary crops consists mainly of acetamiprid; the absence of metabolites IM-1-4 and IM-1-5 in honey was confirmed by the submitted residue trials. (-)
Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and the stability of acetamiprid during storage, the residue definitions for plant products were proposed as 'acetamiprid' for both enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products as well as honey. The current enforcement residue definition in Regulation (EC) No 396/2005 is also acetamiprid. (-)
Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues of acetamiprid at or above 0.01 mg/kg (LOQ) in the crops assessed in these applications as well as in honey according to the enforcement residue definition (zRMS: 'acetamiprid').

Number of trials available for intended uses fulfils the requirements for northern Europe.

The proposed and accepted uses of acetamiprid in the formulation LEPTOSAR 200 SL do not represent unacceptable acute and chronic risks for the consumer.

As residues of acetamiprid do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

According to EFSA Journal 2016;14(2):4385 rape seeds, wheat grain, pulses and their by-products can be fed to livestock and therefore a potential carry-over of residues into food of animal origin was assessed. The dietary burdens for livestock were recently calculated under Article 12 MRL review and were now updated with residues in the feed crops under consideration from the intended uses. As residues in oilseed rape, wheat and pulses do not affect the calculated dietary burdens, a modification of the MRLs proposed

for animal commodities under Article 12 MRL review is not necessary.
According to the applicant: The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

7.1.2.2 Summary for LEPTOSAR 200 SL

Table 7.1-4: Information on LEPTOSAR 200 SL (KCA 6.8)

Crop	PHI for LEPTOSAR 200 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for LEPTOSAR 200 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid		
Winter/ spring oilseed rape, white mustard, black mustard, Chinese mustard, turnip rape	~~NR~~	~~NR~~	F	Although in case of oilseeds or cereals PHI specified in days is commonly in use, it is also acceptable here is setting a PHI by time elapsing between last treatment and harvest of the crop.
Maize, ~~sugar maize Zea mays L. con-var. saccharata Koern.,~~ Popcorn, sorghum, proso true millet	~~NR~~	~~NR~~	F	
Cereals	~~NR~~	~~NR~~	F	
Flax	~~NR~~	~~NR~~	F	
Common hemp	~~NR~~	~~NR~~	F	
Soybean	~~NR~~	~~NR~~	F	
Poppy seeds	~~NR~~	~~NR~~	F	
Sunflower seeds	~~NR~~	~~NR~~	F	
Pumpkin seeds	~~NR~~	~~NR~~	F	
Tomato, aubergine, paprika	3	Y	Accepted	
Wild apple	14	Y		
Pear, Chinese pear	14	Y		
Qince, medlar	14	Y		
Sour cherry, sweet cherry	14	Y	Accepted	
Peach, nectarine apricot	14	Y		
Plum	14	Y	Accepted	
Hazelnut	14	Y		
Walnut	14	Y		
Tobacco	NR	NR		

Crop	PHI for LEPTOSAR 200 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for LEPTOSAR 200 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid		
Common osier, Purple willow	NR	NR		
Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	NR	NR		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

According to EFSA Journal 2021;19(9):6830 the nature of residues in rotational crops (confined studies) has been evaluated during the peer review (EFSA, 2016). Since acetamiprid has a low persistence in soil (highest field DT90 43 days and 20°C lab DT90 54 days), the metabolism study in rotational crops was not conducted with acetamiprid but using the more persistent soil metabolite IM-1-5 (DT50 ranging from 319 to 663 days). In the different rotational crops investigated (wheat, turnip, spinaches), the metabolite IM-1-5 was the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. The field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha (1.5N overdosed with respect to the critical use under consideration), demonstrated that acetamiprid and metabolite IM-1-5 are not expected to be present in rotational crops (EFSA, 2016). Considering that the conditions of application of the representative uses assessed during the renewal cover the new intended uses, this conclusion is still considered relevant in the framework of the present assessment; therefore, no further information is required.

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for LEPTOSAR 200 SL
Crop group	Led by acetamiprid	
All	NR	No comment

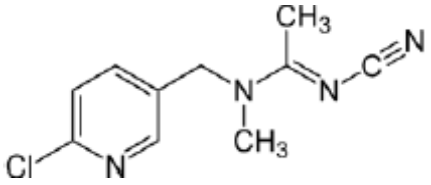
NR: not relevant

Assessment

7.2 Acetamiprid

General data on acetamiprid are summarized in the table below

Table 7.2-1: General information on acetamiprid

Active substance (ISO Common Name)	Acetamiprid
IUPAC	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Chemical structure	
Molecular formula	$C_{10}H_{11}ClN_4$
Molar mass	222.68 g/mol
Chemical group	Neonicotinoid
Mode of action (if available)	Systemic with translaminar activity having both contact and stomach action. Acetylcholine receptor (nAChR) agonist.
Systemic	Yes
Company (ies)	Nisso Chemical Europe GmbH *
Rapporteur Member State (RMS)	NL
Approval status	Approved Date of (01/03/2018) and reference to decision (Commission Implementing Regulation (EU) 2018/113) https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520336385887&uri=CELEX:32018R0113
Restriction	-
Review Report	SANTE/10502/2017 Rev 4 13 December 2017
Current MRL regulation	Regulation (EC) No 2019/88
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes**
EFSA Journal: conclusion on article 12	Yes**
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2016 - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato	High water content	12 months	Goller G, 1999
Apple	High water content	12 months	Gieseke, L.D., 1999
Cabbage	High water content	12 months	
Cucumber	High water content	12 months	
Head lettuce	High water content	15 months	
Cotton seed	High oil content	12 months	
Fodder peas	High protein content	12 months	Jean-Baptiste C., 2009
Cereals	High starch content	8 months	EFSA Journal 2021;19(9):6830
Orange	High acid content	12 months	Gieseke, L.D., 1999

Conclusion on stability of residues during storage

All data on the stability of residues are active substance data and were evaluated in the EU review of acetamiprid. Based on storage stability studies it can be concluded that acetamiprid residues are stable for at least one year in different matrices tested.
No further review is required.
zRMS: Agreed.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No study on the stability of residues in sample extracts of oilseed rape, wheat and maize was conducted. It can be assumed that samples were analysed within 24 hours of preparation.
zRMS: Agreed.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Eggplant	^{14}C-acetamiprid	foliar treatment, F	9 g as/100L	1	7 and 14 days		Saito, H.; 1997
	Apple		foliar treatment, F	208 g as/2000L/ha	1	0, 7, 14, 28, 62 and 90		Saito, H.; 1997
				104 g as/1000L/ha	1	0, 14, 28 and 62		
Leafy vegetables	Cabbage		foliar treatment, F	301.5 g as/1500L/ha	1	0, 7, 14, 21, 28 and 63		Saito, H.; 1997
				5.94 kg as/ha	1	7, 14 and 28		Saito, H.; 1997
				298.5 ga as/1500L/ha	1	0, 7, 14, 28 and 63		Kawai,T.; 1995
Root and tuber vegetables	Carrot		foliar treatment, F	100 g as/ha	2	14 days		McMillan-Staff, S.L., Austin, D.J. and Lingwood, A., 1997
Pulses and oilseeds	Cotton		foliar treatment, F	123 g as/ha / 1.23 kg as/ha	4	14 and 28		Miller N., 1999

Summary of plant metabolism studies reported in the EU

Metabolism is primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups, using 14C-acetamiprid applied by dotting to the surface of the leaves and fruits (aubergine, apple), by spraying (cabbage, carrot, cotton) or using soil application (cabbage). In all plant parts acetamiprid was identified as the major component of the radioactive residues (total radioactive residue (TRR)) accounting for ca. 30–90% TRR 14–90 days after the last application, except in head cabbage where the 6-chloronicotinic acid metabolite (IC-0) was the sole component identified, representing 46% TRR (0.023 mg eq/kg) and in cotton seeds (24% TRR at harvest, 0.27 mg/kg). IC-0 was also detected in carrot roots (26% TRR, 0.02 mg/kg). Other identified metabolites were observed at low levels, accounting mostly for less than 5% TRR, except

metabolites IM-1-4 in immature carrot leaves (43% TRR). Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT90) 43 days and 20°C lab DT90 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT50) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

Conclusion on metabolism in primary crops

Since acetamiprid was identified by far, as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite was concluded to be covered by the toxicity of the parent acetamiprid, the plant residue definitions for monitoring and risk assessment were limited to acetamiprid. These residue definitions are identical to the definitions proposed in the framework of the review of the existing maximum residue levels (MRLs) under Article 12 of Regulation (EU) No 396/2005 (EFSA, 2011b) and implemented in the EU legislation.
All metabolism data are active substance data and are presented in Draft Assessment Report (DAR) for acetamiprid (March 2001) and were evaluated in the EU review of acetamiprid.
Additional studies are not regarded as necessary.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Summary of metabolism metabolism in rotational crops reported in the EU

DAR 2001: the calculated by the rapporteur DT_{90}value of 20.2 days indicates that less than 10% of acetamiprid will be present after 30 days in soil. Therefore, no studies on succeeding or rotational crops are needed for acetamiprid.

The DT_{90} value for acetamiprid is less than 100 days (trigger value). However, soil metabolite IM-1-5 was found to be more persistent. It was noted that formation of metabolite IM-1-5 occurred only in the soils stated to be calcareous (pH > 7). Although, calcareous soils are not just soils with a high pH but also have other distinguishing properties like a $CaCO_3$ content of often more than 15%. The map of topsoil pH (Fig. 1) shows a clear influence of the geochemical makeup of soil parent material. Higher pH levels occur on areas where carbonate rocks are present; this is particularly obvious in areas where soil erosion can enhance the influence of the parent material such as in the area surrounding the Mediterranean Sea. The occurrence of alkaline soils in Southern Europe confirms also the map of topsoil $CaCO_3$ content presented on Figure 2.

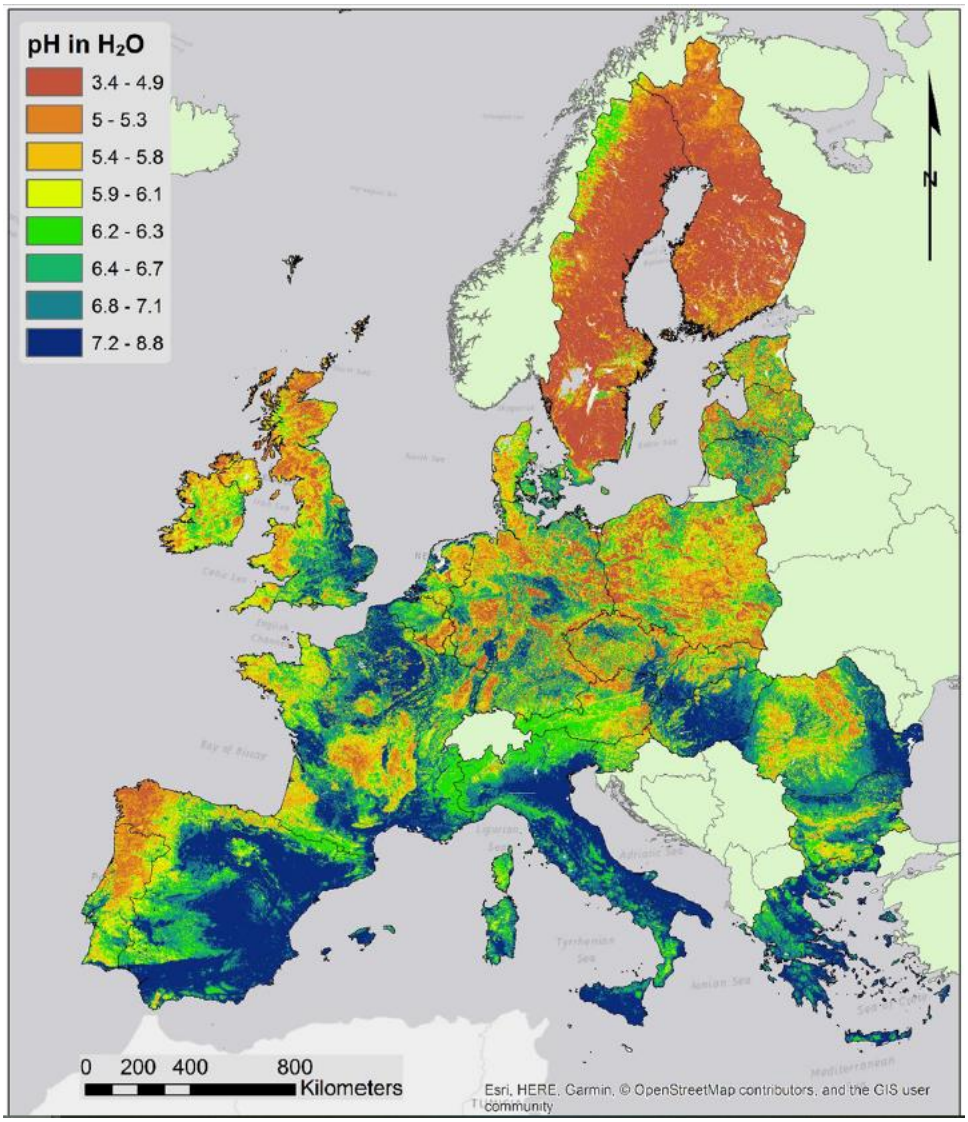


Figure 1. The map of topsoil pH[1]

[1] (Mapping LUCAS topsoil chemical properties at European scale using Gaussian process regression, Cristiano Ballabioa,⁎, Emanuele Lugatoa, Oihane Fernández-Ugaldea, Alberto Orgiazzia, Arwyn Jonesa, Pasquale Borrellib, Luca Montanarellaa, Panos Panagosa, Geoderma 355 (2019) 113912)

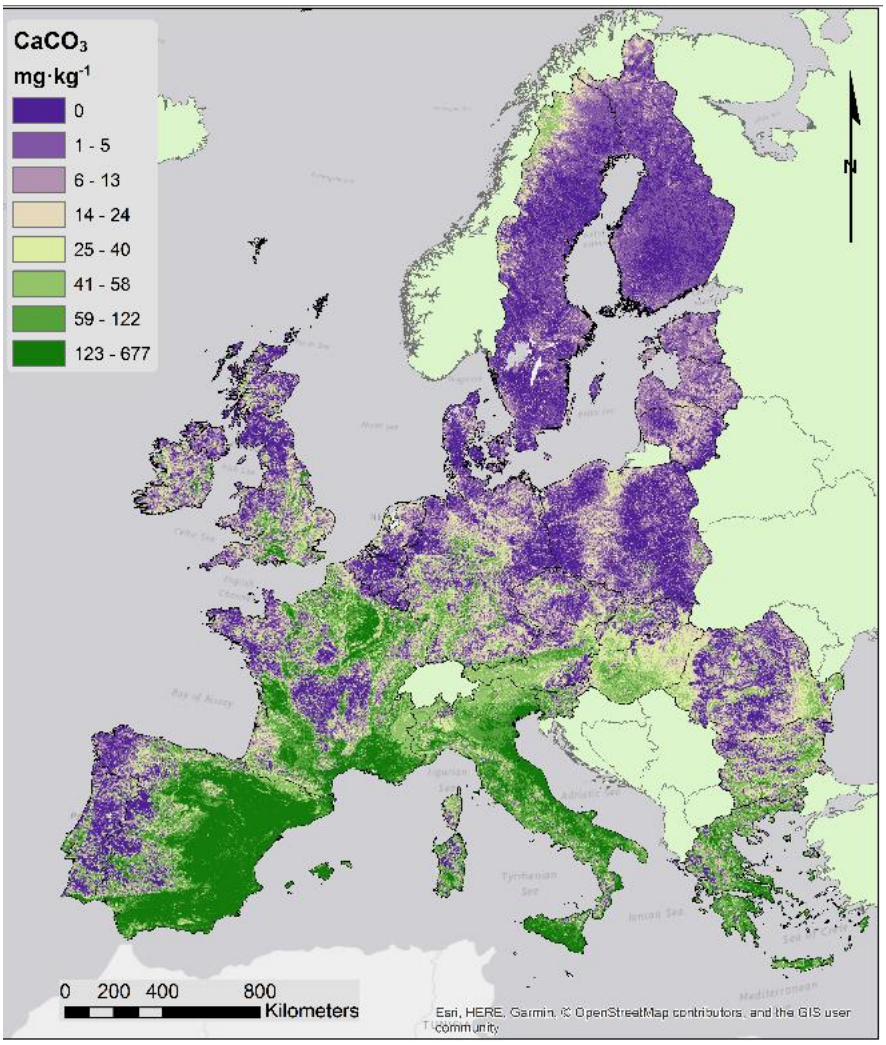


Figure 2. Map of topsoil $CaCO_3$ content[2]

Analyses of National Chemical and Agricultural Station show that the structure of soil in Poland is dominated by soils very acidic (pH < 4.5) and acidic (pH 4.6 – 5.5). The total share of these two groups in the soil structure in Poland is amounted to 44%. The causes of soil acidification in Poland are both natural and anthropogenic. The following table shows structure of soil in Poland:

Table 7.2-4 Structure of soil reaction in Poland[3]

Description	No of samples	Tested area	Soil reaction [%]				
			very acidic pH < 4.5	acidic pH 4.6 – 5.5	slightly acidic pH 5.6 – 6.5	neutral pH 6.6 – 7.2	alkaline pH > 7.2
Poland	**1592200**	**3742,5**	**16**	**28**	**32**	**16**	**8**
Lower Silesia	124413	355,3	10	26	41	16	7
Kuyavia-Pomerania	144641	373,2	8	20	31	24	17
Lublin	118738	119	21	27	24	15	13
Lubusz	44347	118,2	12	33	37	12	6

[2] https://esdac.jrc.ec.europa.eu/public_path/CaCO3.png
[3] *Consumption of lime fertilizers in Poland and the demand for soil liming*, Arkadiusz Piwowar, Wroclaw University of Economics and Business

Lodzkie	79834	122,5	27	35	25	9	4
Lesser Poland	45355	41,2	24	28	22	14	12
Masovia	120437	221,5	25	32	25	13	5
Opole	104751	228,3	3	17	56	20	4
Subcarpathia	72983	96,3	31	33	21	11	4
Podlaskie	58440	124,7	23	35	25	13	4
Pomerania	110819	305,4	13	37	31	14	5
Silesia	44999	305,4	15	26	40	15	4
Świętokrzyskie	37470	41,7	17	22	23	20	18
Warmia-Masuria	134402	307,3	13	33	32	18	4
Greater Poland	216959	581,8	15	27	33	15	10
West Pomerania	133612	400,9	11	30	33	16	10

Calcareous soils and their varieties accounts for a 1.6% share in agricultural production area in Poland (*Smreczak B., Jadczyszyn J., Kabała C., Agricultural suitability of rendzinas in Poland, 2018*). Some of these soils show very good agricultural properties. Most of them are soils rich in nutrients and humus. Nevertheless, some of them contain high natural concentrations of trace elements, causing justified concerns about the quality of the crops produced. Presence of high concentrations of trace elements in calcareous soils affects the assessment of the agricultural suitability of these soils by farmers. It is the cause of their fallow or complete suspension of agricultural production on this kind of soil. Location of calcareous soil in the sculpted areas causes additional challenges for agriculture related to the implementation of such soil cultivation systems that would prevent the destruction of the humus layer.
Based on the occurrence of the calcareous soils mainly in upland, submontane and mountains areas, concerns about quality of the crops produced on such areas it is unlikely that crops, for which authorization of Leptosar 200 SL is applied, will be grown on this type of soil. Nevertheless, to prevent formation of metabolite IM-1-5 after application of product contained acetamiprid it is proposed to add to the label following precautions: “Do not apply on calcareous soils (pH > 7)”.

Conclusion on metabolism in rotational crops

Based on the provided data no studies on succeeding or rotational crops are needed for acetamiprid and its metabolite.
zRMS: Agreed.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (95.6-93.3%)	McMillan-Staff, Austin, D.J., 1997
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (95.1-95.59%)	
Sterilisation (20 minutes, 120°C, pH 6)	Parent (98.08-97.57%)	

Conclusion on nature of residues in processed commodities

All data on the nature of residues in processed commodities are active substance data and were evaluated in the EU review of acetamiprid. Based on these studies it can be concluded that processing by pasteurisation, baking, brewing, boiling and sterilisation of plant materials and particularly citrus, containing acetamiprid residues, is unlikely to result in the production of any significant metabolites.
No further review is required.
zRMS: Agreed.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruit crops (Eggplant, apple) Root crops (Carrot) Leafy crops (Cabbage) Pulses/Oilseeds (Cotton)
Rotational crops covered	Turnip, spinach, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes The only [^{14}C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity.
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Acetamiprid (Regulation n°2019/88) **
Plant residue definition for risk assessment	Acetamiprid (EFSA 2018)***
Conversion factor from enforcement to RA	1 (RMS, 2015, EFSA 2016)

** A more recent proposal by EFSA may be provided as additional information (EFSA RO 2018).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

See, Final Renewal report for the active substance acetamiprid (SANTE/10502/2017 Rev 4 of 13 December 2017) and the opinion reported in EFSA Journal 2021;19(9):6830
zRMS: Agreed.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow /Goat	[14C]- (Acetamiprid)	2	1 and 10 mg/kg feed/day	7	Milk	twice daily	1997
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[14C]- (Acetamiprid)	5	1 and 10 mg/kg feed/day	14	Eggs	daily	1997
						Excreta	daily	
						Tissues	at sacrifice	

Summary of ~~plant~~ animal metabolism studies reported in the EU

In the two livestock studies, the fate of acetamiprid when administered to goats and hens following a daily oral administration regime at 1 ppm (1 mg/kg) and 10 ppm (10 mg/kg) in the diet for 7 days (lactating goats) and 14 days (laying hens) has been investigated. During the course of the dose administration, for both species, 93% of the dose was recovered in the excreta resulting in low tissue residues.
Over the same period of time, the highest residue concentration in the milk from the low dose goat was found to be 0.009 µg/g acetamiprid equivalent and that in the milk from the high dose goat 0.179 µg/g equivalent. At both dose levels steady state was achieved within 1 day to 3 days following the first dose. In the hen, the highest residue concentration in egg yolk was found to be 0.087 µg/g equivalent and 0.944 µg/g equivalent for the low and high dose groups respectively. Similarly, the highest residue concentration in egg white was found to be 0.031 µg/g equivalent and 0.369 µg/g equivalent for the low and high dose groups respectively. At both dose levels steady state was achieved within 4 days to 8 days following the first dose. These results demonstrate that elimination via milk and eggs was of low importance.
At approximately 23 hours following the last dose administration, for both species, tissue residue concentrations were found to be low. For the goat - low dose: residues in all edible tissues were found to be 0.010 µg/g equivalent, and in the high dose the residues were found to be: liver, kidney, muscle and fat: 0.493 µg/g equivalent, 0.355 µg/g equivalent, 0.064 µg/g equivalent and 0.012 µg/g equivalent respectively. For the hen - low dose: residues in all edible tissues were found to be 0.035 µg/g equivalent, and for the high dose the residues were found to be: liver, muscle, fat and skin plus fat: 0.597 µg/g equivalent, 0.090 µg/g

equivalent, 0.009 µg/g equivalent and 0.105 µg/g equivalent respectively. No evidence for accumulation or binding of these residues in any matrix, including blood, was seen.
With regard to the metabolism of the absorbed portion of the dose, the same mechanisms were found to be involved for both species. The metabolite investigations conducted showed these mechanisms, in common with the rat, to include initial N-demethylation of the parent compound followed by sequential hydrolysis of the cyano-methylacetamidine moiety. Further metabolism (Phase II) of these primary metabolites was not in evidence. As far as could be established the metabolite profile for both species was the same at both dose levels.

Conclusion on metabolism in livestock

Following the repeated oral administration of acetamiprid to lactating goats and laying hens a high proportion of the dose was eliminated in the excreta. That part of the dose that was absorbed was, for both species, extensively metabolised and rapidly eliminated resulting in low to very low tissue residues. Elimination via milk or eggs was very much a minor route. The metabolic mechanisms found to be in evidence for both the goat and hen were consistent with those found in the rat. There was no evidence to suggest that there was any accumulation or binding of acetamiprid or its metabolites in milk, eggs or the edible tissues of the animals used in these studies.
All data on the nature of residues in livestock are active substance data and were evaluated in the EU review of acetamiprid.
No further review is required.
zRMS: Agreed.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	4-8 days to reach a steady state in eggs
	1-3 days to reach a steady state in milk
Animal residue definition for monitoring	Sum of acetamiprid and metabolite IM-2-1 (Ndesmethyl-acetamiprid), expressed as acetamiprid (Regulation n°2019/88)*
Animal residue definition for risk assessment	Sum of acetamiprid and metabolite IM-2-1 (Ndesmethyl-acetamiprid), expressed as acetamiprid (EFSA 2016)**
Conversion factor	1 (RMS, 2015) Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products. (EFSA 2016)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO 2018)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
zRMS: Agreed.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of LEPTOSAR 200 SL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape extrapolated to white mustard, black mustard, Chinese mustard, turnip rape, flax, common hemp, soybean, poppy seeds, sunflower, pumpkin seeds (permissible conditions of extrapolations	New trials	N-EU	Trials GAP: 1 x 0.060 kg as/ha, PHI 35-64d, outdoor 4 x < 0.01 E=RA	N/A				
	Overall supporting data for cGAP	N-EU	4 x < 0.01	0.01	0.01	0.01	0.4	Yes

may vary)								
Maize extrapolated to ~~sugar maize~~, Popcorn, sorghum, proso true millet	New trials	N-EU	Trials GAP: 1 x 0.06 kg as/ha, PHI 31-73d, outdoor 4 x < 0.01 E=RA	N/A				
	Overall supporting data for cGAP	N-EU	4 x < 0.01	0.01	0.01	0.01	0.01	Yes
Wheat extrapolated to Triticale, durum, spelt, einkorn, emmer wheat	New trials	N-EU	Trials GAP: 1 x 0.04 kg as/ha, PHI 19-40, outdoor 4 x < 0.01 E=RA	N/A				
	Overall supporting data for cGAP	N-EU	4 x < 0.01	0.01	0.01	0.01	0.1	Yes
Barley ~~extrapolated from wheat~~ (barley is not included in the intended GAP)	New trials	N-EU	Trials GAP: 1 x 0.04 kg as/ha, PHI 19-40, outdoor 4 x < 0.01 E=RA	N/A				
	Overall supporting data for cGAP	N-EU	4 x < 0.01	0.01	0.01	0.01	0.05	Yes
Rye extrapolated from wheat	New trials	N-EU	Trials GAP: 1 x 0.04 kg as/ha, PHI 19-40, outdoor 4 x < 0.01 E=RA	N/A				
	Overall supporting data for cGAP	N-EU	4 x < 0.01	0.01	0.01	0.01	0.01	Yes

Wild apple, pear, chinese pear extrapolated from apples	DAR, 2001	N-EU	Trials GAP: 2 x 0.075 kg as/ha, PHI 14, outdoor 0.01, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071 E=RA	0.031	0.071	0.103	0.4	Yes
	Overall supporting data for cGAP		0.01, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071					
Quinces, medlar extrapolated from apples	Overall supporting data for cGAP	N-EU	0.01, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071	0.031	0.071	0.103	0.8	Yes
Sweet and sour cherries (extrapolation from 4 cherries and 4 apples)	DAR, 2001	N-EU	Trials GAP: 2 x 0.075 kg as/ha, PHI 14, outdoor 0.038, 0.040, 0.055, 0.067 E=RA	0.055	0.067	0.15	1.5	Yes
	Overall supporting data for cGAP		0.038, 0.040, 0.055, 0.067					
Tomatoes	DAR, 2001	S-EU	Trials GAP: 2 x 0.090 kg as/ha, PHI 3, indoor 0.010, 0.011, 0.016, 2 x 0.022, 0.041, 0.049, 0.081 E=RA	0.022	0.081	0.129	0.5	Yes
	Overall supporting data for cGAP		0.010, 0.011, 0.016, 2 x 0.022, 0.041, 0.049, 0.081					
Peppers	DAR, 2001	S-EU	Trials GAP: 2 x 0.090 kg as/ha, PHI 3, indoor 0.024, 0.033, 0.079, 0.1, 0.1, 0.12, 0.15, 0.19 E=RA	0.1	0.19	0.3	0.3	Yes
	Overall supporting		0.024, 0.033, 0.079, 0.1, 0.1, 0.12, 0.15, 0.19					

	data for cGAP							
Aubergines extrapolated from apples	DAR, 2001	S-EU	Trials GAP: 3 x 0.090 kg as/ha, PHI 3, indoor E=RA 0.015, 0.079, 0.087	0.079	0.087	0.16	0.2	Yes
	Overall supporting data for cGAP		0.010, 0.011, 0.016, 2 x 0.022, 0.041, 0.049, 0.081, 0.015, 0.079, 0.087					
Peaches, nectarines extrapolated from apples and plums	Overall supporting data for cGAP	N-EU	5 x < 0.010, 0.01, 0.011, 0.017, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071	0.025	0.071	0.096	0.2	Yes
Apricots extrapolated from apples and plums	Overall supporting data for cGAP	N-EU	5 x < 0.010, 0.01, 0.011, 0.017, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071	0.025	0.071	0.096	0.8	Yes
Plums	DAR, 2001	N-EU	Trials GAP: 2 x 0.050 kg as/ha, PHI 14, outdoor 5 x < 0.010, 0.011, 0.017 E=RA	0.01	0.017	0.022	0.03	Yes
	Overall supporting data for cGAP		5 x < 0.010, 0.011, 0.017					
Hazelnuts, walnuts (extrapolation from apples and stone fruits)	Overall supporting data for cGAP	N-EU	5 x < 0.010, 0.01, 0.011, 0.017, 2 x 0.02, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.04, 2 x 0.056, 0.071	0.025	0.07	0.07	0.07	Yes

* Source of EU MRL: Regulation (EC) No 2019/88

Tomato

Tomato is a major crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum eight trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in tomatoes because of existing trials in DAR. Eight residue trials on tomato were reviewed during the Annex I inclusion process. Thus number of available trials fulfils the requirements for tomato in N-EU. For more details about trials evaluated in the DAR please refer to the table below.

Table 7.2-10: Trials on tomato evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)			PHI	Residues (mg/kg)
		1ST appl	2ND appl	3RD appl		
1. R&D/CRLD/AN/kd/9716021 (1997), Spain	3	0.091	0.091	0.090	3	0.081
2. R&D/CRLD/AN/kd/9715986 (1997), Italy	2	0.093	0.091	-	3	0.016
3. R&D/CRLD/AN/dbe/9716514 (1997), France	2	0.090	0.090	-	3	0.049
4. R&D/CRLD/AN/dbe/9716514 (1997), France	2	0.090	0.090	-	3	0.022
5. R&D/CRLD/AN/dbe/9716513 (1997), France	2	0.084	0.088	-	3	0.011
6. R&D/CRLD/AN/dbe/9716514 (1997), France	2	0.090	0.090	-	3	0.022
7. R&D/CRLD/AN/bva/0015356 (2000), Italy	2	0.102	0.089	-	3	0.010
8. SIP 1224 (2000), Spain	2	0.093	0.090	-	3	0.041

Studies was performed for indoor grown tomatoes in Southern Zone. Growing protected crops requires an optimum range in temperature, independent from the geographical region therefore for the purpose of use in greenhouses, one residue zone is applied across the EU. Accordingly studies presented in DAR are sufficient to support registration of Leptosar 200 SL in Northern Zone for glasshouse use. The application rates for the trials presented in DAR are higher than the maximum recommended rate of Leptosar 200 SL (1 x 60 g a.s./ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration of Leptosar 200 SL.

Aubergine

Aubergine is a minor crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum four trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in aubergine because of existing trials in DAR. Three residue trials on aubergine were reviewed during the Annex I inclusion process. Moreover there is possibility of extrapolation to aubergine with 4 trials on tomatoes. Thus number of available trials fulfils the requirements for aubergine in N-EU. For more details about trials evaluated in the DAR please refer to the table below.

Table 7.2-11: Trials on aubergine evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)			PHI	Residues (mg/kg)
		1ST appl	2ND appl	3RD appl		
1. R&D/CRLD/AN/kd/9716020 (1997), Spain	3	0.09	0.09	0.09	3	0.079
2. R&D/CRLD/AN/kd/9716020 (1997), Spain	3	0.09	0.09	0.09	3	0.087
3. R&D/CRLD/AN/kd/9716020 (1997), Italy	2	0.093	0.103	-	3	0.015

Studies was performed for indoor grown aubergines in Southern Zone. Growing protected crops requires an optimum range in temperature, independent from the geographical region therefore for the purpose of use in greenhouses, one residue zone is applied across the EU. Accordingly studies presented in DAR are sufficient to support registration of Leptosar 200 SL in Northern Zone for glasshouse use. The application rates for the trials presented in DAR are higher than the maximum recommended rate of Leptosar 200 SL (1 x 60 g a.s./ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration of Leptosar 200 SL.

~~Paprika~~ Pepper

Paprika is a major crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum eight trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in paprika because of existing trials in DAR. Five residue trials on peppers were reviewed during the Annex I inclusion process. Moreover paprika is a minor crop in Poland. Thus number of available trials fulfils the requirements for paprika in N-EU. For more details about trials evaluated in the DAR please refer to the table below.

Table 7.2-12: Trials on paprika evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)			PHI	Residues (mg/kg)
		1ST appl	2ND appl	3RD appl		
1. R&D/CRLD/AN/kd/9715753 (1997), Spain	3	0.092	0.099	0.098	3	0.12
2. R&D/CRLD/AN/kd/9716013 (1997), Italy	2	0.093	0.103	-	3	0.024
3. R&D/CRLD/AN/zk/9716441 (1997), Spain	2	0.121	0.120	-	3	0.15
4. R&D/CRLD/AN/zk/9716441 (1997), Spain	2	0.120	0.121	-	3	0.19
5. SIP 1225 (2000), Spain	2	0.089	0.91	-	3	0.079

Studies was performed for indoor grown paprika in Southern Zone. Growing protected crops requires an optimum range in temperature, independent from the geographical region therefore for the purpose of use in greenhouses, one residue zone is applied across the EU. Accordingly studies presented in DAR are sufficient to support registration of Leptosar 200 SL in Northern Zone for glasshouse use. The application rates for the trials presented in DAR are higher than the maximum recommended rate of Leptosar 200 SL (1 x 60 g a.s./ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration of Leptosar 200 SL.

Wild apple, pear, quince, medlar

Wild apple, quince and medlar are minor crops in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum four trials are necessary to cover Northern Europe. Pear is a major crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum eight trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in pome fruits because of existing trials in DAR. Fourteen residue trials on apples were reviewed during the Annex I inclusion process and could be extrapolated to wild apple, pear and quince. Thus number of available trials fulfils the requirements for pome fruits in N-EU. For more details about trials evaluated in the DAR please refer to the table below.

Table 7.2-13: Trials on apple evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)		PHI	Residues (mg/kg)
		1ST appl	2ND appl		
1. R&D/CRLD/AN/kd/9715990 (1997), N. France	2	0.072	0.073	14	0.020
2. R&D/CRLD/AN/kd/9715990 (1997), N. France	2	0.075	0.075	15	0.031
3. R&D/CRLD/AN/kd/9715990(1997), N. France	2	0.075	0.075	15	0.025
4. R&D/CRLD/AN/kd/9716012 (1997), N. France	2	0.075	0.072	14	0.020
5. R&D/CRLD/AN/kd/9716012 (1997), N. France	2	0.075	0.075	14	0.056
6. R&D/CRLD/AN/kd/9716012 (1997), N. France	2	0.075	0.075	14	0.026
7. R&D/CRLD/AN/kd/9716024 (1997), UK	2	0.078	0.078	15	0.031
8. R&D/CRLD/AN/dbe/9716245 (1997), UK	2	0.078	0.078	15	0.040
9. R&D/CRLD/AN/dbe/9716246 (1997), Netherlands	2	0.085	0.092	14	0.071

10. R&D/CRLD/AN/dbe/9716246 (1997), Netherlands	2	0.084	0.085	14	0.030
11. R&D/CRLD/AN/dbe/9716757 (1997), N. France	2	0.091	0.087	14	0.034
12. R&D/CRLD/AN/dbe/9716757 (1997), N. France	2	0.077	0.080	14	0.056
13. R&D/CRLD/AN/mba/0015360 (2000), N. France	1	0.077	-	14	0.010
14. R&D/CRLD/AN/mba/0015360 (2000), N. France	2	0.077	0.077	14	0.030

The application rates for the trials presented in DAR are the higher than the maximum recommended rate of Leptosar 200 SL (2 x 25 g as/ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration for Leptosar 200 SL.

Plum

Plum is a major crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum eight trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in plums because of existing trials in DAR. Seven residue trials on plums were reviewed during the Annex I inclusion process. Moreover, there is possible to extrapolate studies to plum with trials on apples and stone fruits, however only for treatments before the edible parts are formed (see also below cherries, apricots, nectarine and peaches). In case of plums since the residue concentrations detected are at about LOQ, 7 trials was accepted as a sufficient number in 'no residue situation'. Therefore, unlike cherries, apricots, nectarine and peaches, the intended GAP for plums can be accepted with no extrapolation and no limitations.
Thus, number of available trials fulfils the requirements for plums in N-EU. For more details about trials evaluated in the DAR please refer to the table below.

Table 7.2-14: Trials on plums evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)		PHI	Residues (mg/kg)
		1ST appl	2ND appl		
1. R&D/CRLD/AN/dbe/9716762 (1997), N. France	2	0.050	0.050	14	<0.010
2. R&D/CRLD/AN/dbe/9716762 (1997), N. France	2	0.050	0.052	14	<0.010
3. R&D/CRLD/AN/kd/9916082 (1999), N. France	2	0.052	0.054	13	<0.010
4. R&D/CRLD/AN/9915526 (1999), N. France	2	0.050	0.050	14	<0.010
5. R&D/CRLD/AN/9915526 (1999), N. France	2	0.049	0.052	15	<0.010
6. R&D/CRLD/AN/mba/0015275 (2000), N. France	2	0.051	0.051	14	0.017
7. R&D/CRLD/AN/mba/0015288 (2000), N. France	2	0.051	0.051	12	0.011

The application rates for the trials presented in DAR are the higher than the maximum recommended rate of Leptosar 200 SL (2 x 25 g as/ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration for Leptosar 200 SL.

Sour cherry, sweet cherry

Cherry is a major crop in Northern Europe (EU guideline Document SANTE/2019/12752). A minimum eight trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in cherries because of existing trials in DAR. Four residue trials on cherries were reviewed during the Annex I inclusion process. Moreover there is possible to extrapolate studies to plum with trials on apples and stone

fruits. Thus number of available trials fulfils the requirements for cherries in N-EU. For more details about trials evaluated in the DAR please refer to the table below (see above in plum text the wider justification of an extrapolation case - not for treatments after BBCH 65.).

Table 7.2-15: Trials on cherries evaluated in the DAR

Trials details	No. of treatments	Application rate (kg a.s./ha)		PHI	Residues (mg/kg)
		1ST appl	2ND appl		
1. R&D/CRLD/AN/kd/9916066 (1999), N. France	2	0.052	0.0502	14	0.038
2. R&D/CRLD/AN/mba/0015257 (2000), N. France	1	0.077	-	14	0.055
3. R&D/CRLD/AN/bva/0015258 (2000), N. France	1	0.077	-	14	0.067
4. R&D/CRLD/AN/bva/0015258 (2000), N. France	1	0.077	-	14	0.040

The application rates for the trials presented in DAR are the higher than or similar as the maximum recommended rate of Leptosar 200 SL (2 x 25 g as/ha). However it should be considered as a worst case. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration for Leptosar 200 SL.

Peach, nectarine, apricot

Peach, nectarine, apricot are a minor crops in Northern Europe (EU guideline Document SANCO 7525/VI/95 – rev. 10.2, 23 September 2016). A minimum four trials are necessary to cover Norther Europe. For Leptosar 200 SL no new trials were conducted in stone fruits because of possibility of extrapolation results from apples and stone fruits. Plenty of residue trials on apples and plums were reviewed during the Annex I inclusion process and are summarised in the tables above. Thus, number of trials carried out of apples and plums fulfils the requirements for stone fruits in N-EU, however not for treatments after BBCH 65.

Hazelnuts and walnuts

Hazelnuts and walnuts are a minor crops in Northern Europe (EU guideline Document SANCO 7525/VI/95 – rev. 10.2, 23 September 2016). A minimum four trials are necessary to cover Northern Europe. For Leptosar 200 SL no new trials were conducted in three nuts because of possibility of extrapolation results from apples and stone fruits. Plenty of residue trials on apples and plums were reviewed during the Annex I inclusion process and are summarised in the tables above. Thus number of trials carried out of apples and plums fulfils the requirements for tree nuts in N-EU.

Tobacco, common osier, purple willow, ~~miscanthus sp.,~~ (no in intended GAP) forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations, christmas trees grown on plantations

Residue studies shall always be performed where plant protection product is to be applied to plants or plant products that are used as food or feed. Leptosar 200 SL will be used for protection of Tobacco, common osier, purple willow, miscanthus sp., forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations, christmas trees grown on plantations therefore no additional studies are necessary to support this use of Leptosar 200 SL.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on oilseed rape, spring oilseed rape, white mustard, black mustard, Chinese mustard, turnip rape, flax, common hemp, soybean, poppy seeds, sunflower, pumpkin seeds, wheat and other cereals, maize, sugar maize, Popcorn, sorghum, proso true millet, wild apple, quince and medlar, sour cherry, sweet cherry, peach, nectarine, apricot, plum, hazelnuts and walnuts are considered

acceptable, for outdoor uses.

According to the available data, the intended uses on aubergine, tomato and paprika are considered acceptable, for indoor uses.

According to EU guidelines, extrapolation to cereal is possible with 4 trials on wheat (number of studies may be reduced to four when the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification), which is the case here.
Extrapolation to Spring oilseed rape, white mustard, black mustard, Chinese mustard, turnip rape, flax, common hemp, soybean, poppy seeds, sunflower, pumpkin seeds is possible with 4 trials on oilseed rape (number of studies may be reduced to four when the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification), which is the case here.
Extrapolation to sugar maize, Popcorn, sorghum, proso true millet is possible with 4 trials on maize (number of studies may be reduced to four when the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification), which is the case here.
Extrapolation to aubergine is possible with 4 trials on tomatoes, which is the case here.
Extrapolation to wild apple, quince and medlar is possible with 4 trials on apples and extrapolation to pear is possible with 8 trials on apples which is the case here.
Extrapolation to sour cherry, sweet cherry, peach, nectarine, apricot, plum, hazelnuts and walnuts is possible with trials on apples and stone fruit which is the case here.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable except those indicated/updated by zRMS – see the final GAP table in overall conclusion.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-16: Input values for the dietary burden calculation (considering the intended uses)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: acetamiprid				
Oilseed rape	0.01	STMR	NR	
Maize	0.01	STMR		
Corn, field (maize) grain	0.01	STMR		
Corn, pop, grain	0.01	STMR		
Corn, field, milled by pdts	0.01	PF=1		
Corn, field, hominy meal	0.01	PF=1		
Corn, field, gluten feed	0.01	PF=1		
Corn, field, gluten meal	0.01	PF=1		

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, triticale, grain	0.01	STMR		
Wheat gluten, meal	0.01	PF=1		
Wheat, milled by-pdts	0.01	PF=1		
Distiller's grain dried	0.01	PF=1		
Canola (rape seed), meal	0.01	PF=1		
Flaxseed/linseed	0.01	PF=1		
Apple pomace wet	0.03	STMR		
Wheat straw	0.535	STMR	0.590	HR
Triticale straw	0.535	STMR	0.590	HR
Rye straw	0.535	STMR	0.590	HR
Barley straw	0.535	STMR	0.590	HR

Table 7.2-17: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Acetamiprid					
Dairy cattle*	0.009	0.009	Wheat straw	0.28	Y
Ram/ewe	0.013	0.015	Wheat straw	0.44	Y
Lamb	0.017	0.019	Wheat straw	0.44	Y
Finishing swine*	0.000	0.000	Corn field milled bypdts	0.01	N
Layer poultry*	0.005	0.005	Wheat straw	0.08	Y

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

The new EU data requirement as published with Regulation (EC) 283/2013 for active substances state the need for feeding studies where intake is above 0.004 mg/kg bw/d. Results of the dietary burden calculation presented above indicate that this trigger is exceed for all animal species despite pigs.
However, the circumstances in which feeding studies are required also have to take into consideration where metabolism studies indicate that residues at levels of above 0.01 mg/kg may occur in edible animal tissue, milk, eggs or fish, taking into account the residue levels in potential feeding items, obtained at the 1 × dose rate, calculated on the dry weight basis.

The calculation of actual occurrence of residues in edible animal tissue, milk, eggs are presented below:

Poultry

Referring to point 7.2.2.5, a study of the metabolism of [14C]- (Acetamiprid) in laying hens dosed at 1 and 10 mg/kg feed/day, corresponding 0.07 and 0.68 mg/kg bw/day, once daily for fourteen consecutive days resulted in the residues in egg yolk of 0.087 µg/g equivalent and 0.944 µg/g equivalent for the low and high dose groups respectively. In other matrices residues were less than in case of egg yolk.
The maximum dietary burden of laying hens calculated using the residue data presented to support this submission (refer to point 7.2.4) is 0.005 mg/kg/bw/day. Taking the dietary burden of laying hens into account, the maximum concentration of acetamiprid in edible tissues and eggs would be <0.01 mg/kg ((0.944 x 0.005)/0.68=**0.007** mg/kg).

Residues of acetamiprid will not therefore exceed 0.01 mg/kg in poultry edible tissues or eggs following uses proposed for registration of PPP, therefore there is no requirement for a livestock feeding study for poultry.

Pigs

Results of the dietary burden calculation presented above indicated that the trigger of 0.004 mg/kg bw/d is not exceed for pigs. Therefore feeding studies on pigs are not required.

Ruminants

Exceedance of the level 0.01 mg/kg occur for ruminants therefore livestock feeding studies are presented below.

Conclusion on feeding studies

Feeding studies shall be provided where metabolism studies indicate that residues at levels of above 0.01 mg/kg may occur in edible animal tissue, milk, eggs. Based on calculations presented above it can be concluded that residues of acetamiprid will not exceed 0.01 mg/kg in poultry edible tissues or eggs following uses proposed for registration of PPP, therefore there is no requirement for a livestock feeding study for poultry.
Livestock feeding studies in ruminants are presented below.

7.2.4.3 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.
Previously evaluated in original DAR livestock feeding studies in ruminants are presented below.

In this study, nine lactating Holstein cows (562 to 688 kg) were orally dosed once daily for 28 consecutive days with encapsulated acetamiprid (purity 99.9%). The nominal dose rates based upon acetamiprid/kg feed intake on a dry matter basis were: 6, 18 and 60 ppm. The measured acetamiprid dose rate was for Group 6 ppm=>5.77 ppm, for Group 18 ppm=>17.4 ppm and for Group 60 ppm=>58.6 ppm. Two cows served as untreated controls.
Feed intake and milk production were recorded daily throughout the study. Milk samples were obtained on days -1, 1, 2, 4, 8, 11, 15, 18, 22, 25 and 27.
Average group daily milk production per cow were: Group 0 ppm: 27.6 kg/day, Group 6 ppm: 21.2 kg/day, Group 18 ppm: 21.4 kg/day and Group 60 ppm: 20.7 kg/day.

The samples were analysed for both acetamiprid and IM-2-1 because prior metabolism studies, have shown that residues of toxicological concern in lactating goats and laying hens are comprised of parent compound (acetamiprid) and IM-2-1 metabolite (N-desmethyl-acetamiprid). When animals were exposed to acetamiprid for 28 consecutive days, acetamiprid residue concentrations in whole milk showed to be dose-dependent and exhibited rapidly increasing concentrations until a plateau was reached in about 1 day. IM-2-1 residue concentrations in whole milk were both dose- and time-dependent, reaching a plateau at about 7 days. IM-2-1 was the predominant residue in milk. The ranges and approximate plateau levels are presented in Table 7.2-18. Residue concentrations according to the residue definition sum of acetamiprid and IM-2-1 are expressed as acetamiprid.

When animals were exposed to acetamiprid for 28 consecutive days, acetamiprid residue concentrations are below LOQ for all tissues at the low dose group (5.77 ppm). On the contrary, IM-2-1 residues were above LOQ in all tissues collected on study day 28. Both, parent compound and IM-2-1 metabolite, in all tissues collected at day 28 were highly dose dependent. Residue concentrations of acetamiprid, IM-2-1 metabolite (N-desmethyl-acetamiprid) and sum of acetamiprid and IM-2-1, expressed as acetamiprid in animal tissues are presented in Table 7.2-18.

Table 7.2-18: Concentration of residues of acetamiprid and N-desmethyl-acetamiprid (IM-2-1) animal tissues in a feeding study in cows

		5.77 mg/kg DM 0.21 mg/kg bw/day			17.4 mg/kg DM 0.63 mg/kg bw/day			58.6 mg/kg DM 2.13 mg/kg bw/day		
		Aceta-miprid [mg/kg]	IM-2-1[1] [mg/kg]	Sum of acetamiprid and IM-2-1[2] [mg/kg]	Aceta-miprid [mg/kg]	IM-2-1 [mg/kg]	Sum of acetam-iprid and IM-2-1 [mg/kg]	Aceta-miprid [mg/kg]	IM-2-1 [mg/kg]	Sum of acetamiprid and IM-2-1 [mg/kg]
1999										
Fat	Animal 1	<0.01	<0.01	<0.02	0.01	0.14	0.16	0.02	0.19	0.22
	Animal 2	<0.01	<0.01	<0.02	<0.01	0.03	0.05	0.01	0.15	0.17
	Animal 3	<0.01	0.06	0.08	<0.01	0.02	0.03	0.06	0.65	0.76
	Mean	<0.01	0.03	0.04	0.01	0.06	0.08	0.03	0.33	0.39
Muscle	Animal 1	<0.01	0.04	0.05	0.03	0.26	0.31	0.06	0.70	0.81
	Animal 2	<0.01	0.04	0.05	0.01	0.09	0.11	0.05	0.99	1.10
	Animal 3	<0.01	0.04	0.05	0.02	0.13	0.16	0.11	1.00	1.18
	Mean	<0.01	0.04	0.05	0.02	0.16	0.19	0.07	0.90	1.03
Kidney	Animal 1	<0.05	0.20	0.26	<0.05	0.81	0.91	0.08	2.10	2.32
	Animal 2	<0.05	0.17	0.21	<0.05	0.54	0.63	0.06	2.40	2.62
	Animal 3	<0.05	0.20	0.26	<0.05	0.61	0.70	0.14	2.40	2.70
	Mean	<0.05	0.19	0.25	<0.05	0.65	0.75	0.09	2.30	2.55
Liver	Animal 1	<0.05	0.10	0.16	0.06	0.58	0.68	0.12	1.60	1.83
	Animal 2	<0.05	0.10	0.16	<0.05	0.29	0.30	0.10	2.40	2.66
	Animal 3	<0.05	0.10	0.16	<0.05	0.31	0.38	0.25	2.40	2.81
	Mean	<0.05	0.10	0.16	0.05	0.39	0.47	0.16	2.13	2.43
Milk, plateau level and range[3]	Animal 1	0.015 (0.01-0.02)	0.05 (0.03-0.06)	0.07 (0.04-0.08)	0.06 (0.05-0.08)	0.23 (0.14-0.30)	0.31 (0.21-0.39)	0.17 (0.15-0.20)	0.72 (0.40-0.80)	0.94 (0.60-1.03)
	Animal 2	0.013 (0.01-0.02)	0.04	0.06 (0.04-0.07)	0.03 (0.03-0.06)	0.15 (0.13-0.17)	0.19 (0.16-0.21)	0.21 (0.18-0.26)	0.95 (0.59-1.00)	1.22 (0.89-1.27)

	Animal 3	0.016 (0.01-0.02)	(0.03-0.05) 0.06 (0.04-0.07)	0.08 (0.05-0.09)	0.05 (0.05-0.06)	0.16 (0.11-0.20)	0.22 (0.17-0.26)	0.19 (0.17-0.23)	0.86 (0.63-1.10)	1.10 (0.86-1.37)
	Mean	0.015	0.05	0.07	0.05	0.18	0.24	0.18	0.84	1.09

[1]Metabolite IM-2-1 = N-desmethyl-acetamiprid
[2]Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as acetamiprid [mg/kg], calculated while considering a molar mass of 222.68 for acetamiprid and 208.65 for N-desmethyl-acetamiprid.
[3]The ranges of residues found in milk are indicated between brackets. The plateau level is the average residue concentration after reaching a plateau. Acetamiprid residue concentrations in whole milk reached a plateau in about 1 day. IM-2-1 and sum acetamiprid and IM-2-1 reached a plateau in about 7 days.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

zRMS: agreed

EFSA Journal 2021;19(9):6830:
(Apart from cereals as a feed) processed mustard seeds may be used as fish feed item according to the working document on the nature of pesticides residues in fish (SANCO/11187/2013, European Commission, 2013). Fish dietary burden from the intake of mustard seed was calculated with the STMR value of 0.03 mg/kg as derived from the submitted residue trials. The maximum dietary burden for common carp and rainbow trout was calculated to be 0.003 and 0.002 mg/kg DM, respectively and the calculated worst-case intakes for both fish species are not significant (< 0.1 mg/kg DM) (Netherlands, 2021) thus demonstrating that further studies investigating the nature and magnitude of residues in fish are not required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

The intended crops may be processed however their residue levels are expected to be < 0.1 mg/kg (see Point 7.2.3 above) and the contribution of each of these commodities to the theoretical maximum daily intake (TMDI) is < 10% of the ADI. Therefore, no processing studies are required for these crops.
No further studies have been performed.
zRMS: agreed

7.2.6 Magnitude of residues in representative succeeding crops

Orchard trees under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required
The rest of crops under consideration can be grown in rotation.
Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.
zRMS: agreed

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of LEPTOSAR 200 SL. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-19: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Acetamiprid				
Oilseed rape	0.4	EU MRL (In force MRL according to Reg. (EU) No 2019/88)	0.4	EU MRL (In force MRL according to Reg. (EU) No 2019/88)
Linseeds, poppy seeds, sunflower seeds, soyabeans, mustard seeds, pumpkin seeds, hemp seeds	0.01		0.01	
Maize, sweet corn	0.01		0.01	
Wheat/triticale	0.1		0.1	
Barley	0.05		0.05	
Common millet, rye, sorghum, other	0.01		0.01	
Hazelnuts, walnuts	0.07		0.07	
Apples, pears	0.031	STMR	0.071	HR
Apricots	0.025	STMR	0.071	HR
Quinces, medlar	0.8	EU MRL (In force MRL according to Reg. (EU) No 2019/88)	0.8	EU MRL (In force MRL according to Reg. (EU) No 2019/88)
Cherries	1.5		1.5	
Peaches	0.2		0.2	
Plums	0.03		0.03	
Tomatoes	0.022	STMR	0.081	HR
Peppers	0.3	EU MRL (In force MRL according to Reg. (EU) No 2019/88)	0.3	EU MRL (In force MRL according to Reg. (EU) No 2019/88)
Aubergines	0.2		0.2	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other commodities of plant and animal origin	various		-	-

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-20: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	98 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	TMDI values do not exceed ADI therefore IEDI calculations are not required.
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: Quinces: 79 % (Children) Peaches :60 % (Adults) Processed commodities: Peaches/canned: 21% (Children) Peaches/canned: 7% (Adults)
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of acetamiprid in the formulation LEPTOSAR 200 SL do not represent unacceptable acute and chronic risks for the consumer.
zRMS: agreed

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA, 2016. Peer review of the pesticide risk assessment of the active substance acetamiprid

SANTE/10502/2017 Rev 4, 13 December 2017. Final Renewal report for the active substance acetamiprid finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 13 December 2017 in view of the renewal of the approval of acetamiprid as active substance in accordance with Regulation (EC) No 1107/20091

SANTE/2019/12752 TECHNICAL GUIDELINES ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)

Acetamiprid Volume 3, Annex B-7: Residue data, March 2001

EFSA Journal 2016;14(2):4385 Modification of the existing maximum residue levels for acetamiprid in various crops.

EFSA Journal 2021;19(9):6830 Modification of the existing maximum residue levels for acetamiprid in various crops.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 6.3/01	M. Kurek	2019	Determination of residues od acetamiprid in/on winter/spring oilseed rape under open field conditions following one and two applications of A-200SL-OR3-CPD in Northern Europe in 2018 428SRPL18R03 SynTech Research Poland GLP Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/02	M. Kurek	2019	Determination of residues od acetamiprid in/on maize under open field conditions following one applications of A-200SL-OR3-CPD in Northern Europe in 2018 428SRPL18R04 SynTech Research Poland GLP Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/03	M. Kurek-Molenda	2020	Determination of residues od acetamiprid in/on winter wheat under open field conditions following one applications of A-200SL-OR3-CPD in Northern Europe in 2019 428SRPL19R02 SynTech Research Poland GLP Unpublished	N	CIECH Sarzyna S.A.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	Owner
KCA 6.1/01	G. Goller	1999	Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below -18 °C – Fortification experiments with active ingredient Document No. RD-00340 A.D.M.E. - Bioanalyses, GLP Not published	N	Nippon Soda
KCA 6.1/02	L.D. Gieseke	1999	NI-25 (acetamiprid): Freezer storage stability of acetamiprid residues in various raw agricultural commodities and processing fractions (plant matrices). Report No. 10201 Horizon Laboratories, GLP Not published	N	Nippon Soda
KCA 6.1/03	C. Jean-Baptiste	2009	Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea. Report No. A7125, Anadiag Laboratories. GLP, not published	N	Nippon Soda
KCA 6.2.1/01	Austin, D.J., McMillan-Staff, S.L., Lingwood, A.	1997	[14C]-NI-25 Metabolism in Carrots Report/file:RPAL Study 11253 Rhône-Poulenc Agriculture Ltd GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1/02	Kawai, T.	1995	NI-25 [CN-14C] – Nature of the Residue in Cabbages Plants Report/file:NCAS N°:2-137 NG Amended Report EC-617-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP : Yes	N	Nippon Soda

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
			Not published		
KCA 6.2.1/03	Saito, H.	1997	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Apples Report/file:NCAS N°:2- 98 Amended Report-742-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1/04	Saito, H.	1997	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Cabbages Plants Report/file:NCAS N°:2- 111 Amended Report EC-743-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1/05	Saito, H.	1997	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Eggplants Nisso Chemical Analysis Service Co, Ltd Report/file:NCAS N°-2- 92 Amended Report N° EC-391-3 GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1/06	Miller N.	1999	Foliarly applied 14Cacetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum). Report No. EC-97-367, Rhone-Poulenc Ag Company. GLP, not published	N	Nippon Soda
KCA 6.2.2-6.2.5/01	xxx	1997	14C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats Report/file: RCC N°: 628132 RCC Umweltchemie AG GLP, GEP : Yes Not published	Y	Nippon Soda

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	Owner
KCA 6.3/01	Sonder K-H	2001	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) - Decline of residues in Sweet Pepper European Union (indoor) 2000 Generated by: Aventis CropScience Report/file: DR 00EUI 606 GLP, GEP : yes Not published	N	ROP
KCA 6.3/02	Sonder K-H	2002	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) – Residue behaviour in Sweet Pepper (indoor) European Union (Southern zone) 2001 Generated by: Aventis CropScience Report/file: 01 RI 612 GLP, GEP : yes Not published	N	ROP
KCA 6.3/03	Baudet L., Yslan F.	1999	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1998 – 1 harvest trial – residues in Plum (fruit without stone). Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9916082 GLP, GEP : yes Not published	N	ROP
KCA 6.3/04	D'AccriscioM., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial United Kingdom – residues in Apple decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716245 GLP, GEP : yes Not published	N	ROP
KCA 6.3/05	D'AccriscioM., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial The Netherlands 1996 – residues in Apple Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715752	N	ROP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
			GLP, GEP : yes Not published		
KCA 6.3/06	Freschi G.	2000	Analysis of NI-25 (Acetamiprid) Residues in Tomato (whole fruit) Generated by: Sipcam Spa Report/file: SIP1224 GLP, GEP : yes Not published	N	Sipcam
KCA 6.3/07	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Italy 1996 – residues in Tomato (greenhouse) – Decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715986 GLP, GEP : yes Not published	N	ROP
KCA 6.3/08	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1996 – residues in Tomato (greenhouse) – Decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716021 GLP, GEP : yes Not published	N	ROP
KCA 6.3/09	D'AccriscioM., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial The Netherlands 1996 – residues in Apple Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716246 GLP, GEP : yes Not published	N	ROP
KCA 6.3/10	Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in Plum (quetsche and mirabelle). Decline Study Generated by: Rhone-Poulenc Agro	N	ROP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
			Report/file: R&D/CRLD/AN/dbe 9716762 GLP, GEP : yes Not published		
KCA 6.3/11	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial United Kingdom 1996 – residues in Apple Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716024 GLP, GEP : yes Not published	N	ROP
KCA 6.3/12	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1997 – residues in Apple. Decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716757 GLP, GEP : yes Not published	N	ROP
KCA 6.3/13	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in tomato (in Greenhouse) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716514 GLP, GEP : yes Not published	N	ROP
KCA 6.3/14	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in tomato (in Greenhouse) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716513 GLP, GEP : yes Not published	N	ROP
KCA 6.3/15	Richard M.,	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1995 – residues in pepper (in Netting)	N	ROP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
	Maestracci M.		Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715753 GLP, GEP : yes Not published		
KCA 6.3/16	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Italy 1996 – residues in pepper (in greenhouse) – decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716013 GLP, GEP : yes Not published	N	ROP
KCA 6.3/17	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1997 – residues in pepper (in greenhouse) – decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716441 GLP, GEP : yes Not published	N	ROP
KCA 6.3/18	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1996 – residues in apple – decline study Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715990 GLP, GEP : yes Not published	N	ROP
KCA 6.3/19	Richard M., Maestracci M.	1999	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1998 – residues in cherry (fruit and stoned fruit) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9916066 GLP, GEP : yes	N	ROP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
			Not published		
KCA 6.3/20	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – residues in apples + processed products Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015360 GLP, GEP : yes Not published	N	ROP
KCA 6.3/21	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1999 – 1 decline study trial – residues in plum (fruit and fruit without stone) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015275 GLP, GEP : yes Not published	N	ROP
KCA 6.3/22	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1999 – 1 decline study trial – residues in plum (fruit and fruit without stone) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015288 GLP, GEP : yes Not published	N	ROP
KCA 6.3/23	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – South/Italy/1999 – 1 harvest study trial – residues in tomato (fruit).(in greenhouse) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/bva 0015356 GLP, GEP : yes Not published	N	ROP
KCA 6.3/24	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – decline study trials – residues in cherries (fruit and stoned fruit)	N	ROP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
			Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015257 GLP, GEP : yes Not published		
KCA 6.3/25	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – harvest study trials – residues in cherries (stoned fruit) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/bva 0015258 GLP, GEP : yes Not published	N	ROP
KCA 6.3/26	D'AccriscioM., Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1996 – residues in Eggplant (greenhouse) Generated by: Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716020 GLP, GEP : yes Not published	N	ROP
KCA 6.3/27	Freschi G.	2000	Analysis of Acetamiprid Residues on Pepper (whole fruit) Generated by: Sipcam Spa Report/file: SIP1225 GLP, GEP : yes Not published	N	Sipcam
KCA 6.5.1/01	McMillan-Staff, Austin, D.J.	1997	[14C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Report/file:RPAL Study 13442 Rhône-Poulenc Agriculture Ltd Not published	N	Nippon Soda
KCA 6.2.2-	xxx	1997	14C -NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral	Y	Nippon Soda

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
6.2.5/02			Administration to Laying Hens Report/file: RCC N°: 628143 Generated by: RCC Umweltchemie AG GLP. GEP : Yes		
KCA 6.4.1-6.4.3/01	xxx	1999	Acetamiprid : Magnitude of Residues in Dairy Cow Milk and Tissues. ABC Laboratories, Inc. Report/file:Study 98514428/File N° 45649 Not published	Y	Nippon Soda

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Acetamiprid

A 2.1.1 Stability of residues

No new or additional studies have been submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Oilseed rape

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2016)	2	42 g a.s./ha	n.r.	1st appl.: BBCH 59 2nd appl.: BBCH 80	n.r.
Intended cGAP (1-5 7-11 13-17 19-23 27-31 34-38 41-45*)	1	60 g a.s./ha	n.r.	BBCH 71	n.r.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1

Comments of zRMS:	The study has been accepted. The objective of the study was to determine residues of acetamiprid in oilseed rape seeds after one and two applications of LEPTOSAR 200 SL. The study conduct with one treatment was consistent with the intended GAP. The one application was made with 60g acetamiprid /ha at BBCH 71. The employed in the study analytical QuEChERS method using for final determination LC-MS/MS was shown to be highly selective, as it includes two parent-daughter ion mass transitions for Acetamiprid, and it yields accurate and

	repeatable results. The LOQ was established at 0.01 mg/kg, interfering signals in control specimen were negligible, and thus the LOD is 0.002 mg/kg. Five recovery determinations were performed at the LOQ (0.01 mg/kg) and at the 50xLOQ (0.5 mg/kg) for OSR. The mean recovery values at the fortification levels of 0.01 mg/kg and 0.5 mg/kg for both ion mass transitions of Acetamiprid were all in the range of 70 – 110 %. All precision values at the fortification levels of 0.01 mg/kg and 0.5 mg/kg for both ion mass transitions were < 20 %. It can be concluded that method fulfils the requirements of SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 and can be applicable as enforcement and data generation method for determination of acetamiprid in oilseed rape. The study was amended 7 times due to minor issues, not affecting the study.

Reference:	KCA 6.3
Report	Determination of residues of acetamiprid in/on winter/spring oilseed rape under open field conditions following one and two applications of A-200SL-OR3-CPD in Northern Europe in 2018, M. Kurek, 2019, 428SRPL18R03
Guideline(s):	Yes (OECD guideline 509, SANCO/825/00, SANCO/3029/99)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four new residue trials in oilseed rape were conducted in the growing season 2018 in different localizations. The test item was oilseed rape seeds samples (different varieties) treated with product A-200SL-OR3-CPd and control samples. The product was applied once at rate of 0.3 L/ha (corresponding to 60 g/ha of acetamiprid).
Specimens (seeds) were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Oilseed rape samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 205 days. Results on residue trials in oilseed rape are detailed summarised in Table A 2.
The residues of acetamiprid in samples treated with A-200SL-OR3-CPd were below the limit of quantification, i.e. 0.01 mg/kg, were below the maximum residue limits, i.e 0.4 mg/kg in oilseed rape.

Detailed method validation is presented in section B5.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
SRPL18-145-428IR Poland N-EU 2018	Oilseed rape Kuga	1) 28 Aug 2017 2) First part of May 3) 30 Jul 2018	1. 60.356	251.5	23.99	27 May 2018	71	Seed	< LOD	64	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 150 days
SRDE18-081-428IR Germany N-EU 2018	Oilseed rape Ability	1) 12 Apr 2018 2) 04-11 Jun 2018 3) 21 Aug 2018	1. 63.47	317.3	20.00	18 Jun 2018	71	Seed	< LOD	64	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 172 days
SRUK18-019-428IR UK N-EU 2018	Oilseed rape DK Exclaim	1) 23 Aug 2017 2) Early May 3) 17 Jul 2018	1. 59.866	249.0	24.04	22 May 2018	71	Seed	< LOD	56	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 185 days
SRHU18-506-428IR Hungary N-EU 2018	Oilseed rape PR45D03	1) 28 Aug 2017 2)Apr-May 2018 3) 27 Jun 2018	1. 56.578	330.0	17.14	23 May 2018	71	Seed	<LOQ	35	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 205 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
< LOD = < 0.002 mg/kg
< LOQ = <0.01 mg/kg

A 2.1.3.2 Maize

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (6, 12, 18, 25-26, 32-33, 39-40, 56*)	1	60 g a.s./ha	n.r.	BBCH 75	n.r.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.2.1 Study 1

Comments of zRMS:	The study has been accepted. The field phase was conducted to determine the residues of acetamiprid in maize at harvest after one application of the product (200 g/L) applied once at a nominal rate of 60 g / ha at BBCH 75. The determination of acetamiprid was performed by LC-MS/MS. The general principles of the analytical procedure were based on the normalized method EN 15662:2008 (“Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method”). The method was successfully validated according to the SANCO Guidelines 3029/99 rev.4 and 825/00, rev. 8.1. in maize: specificity, linearity, accuracy and precision of the method were fully demonstrated for the analysis of acetamiprid (see B5). No acetamiprid residues were detected in any treated or untreated samples of maize from 4 trials conducted within this study.

Reference:	KCA 6.3
Report	Determination of residues of acetamiprid in/on maize under open field conditions following one applications of A-200SL-OR3-CPD in Northern Europe in 2018, M. Kurek, 2019, 428SRPL18R03
Guideline(s):	Yes (OECD guideline 509, SANCO/825/00, SANCO/3029/99)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four new residue trials in maize were conducted in the growing season 2018 in different localizations. The test item was maize kernels samples (different varieties) treated with product A-200SL-OR3-CPd and control samples. The product was applied once at rate of 0.3 L/ha (corresponding to 60 g/ha of acetamiprid). Specimens (kernels) were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Maize samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 166 days. Results on residue trials in oilseed rape are detailed summarised in Table A 4.
The residues of acetamiprid in samples treated with A-200SL-OR3-CPd were below the limit of detection, i.e. 0.002 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in maize.

Detailed method validation is presented in section B5.

Table A 4: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
SRPL18-146-428IR Poland N-EU 2018	Maize Norico	1) 26 May 2018 2) - 3) 08 Nov 2018	61.111	305.6	19.99	27 Aug 2018	75	Kernels	<LOD	73	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 146 days
SRDE18-082-428IR Germany N-EU 2018	Maize LG30258	1) 25 Apr 2018 2) - 3) 15 Oct 2018	60.270	502.2	12.00	07 Aug 2018	75	Kernels	<LOD	69	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 166 days
SRhu18-507-428IR UK N-EU 2018	Maize Surreal	1) 20 Apr 2018 2) - 3) 14 Sep 2018	63.991	373.3	17.14	14 Aug 2018	75	Kernels	<LOD	31	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 159 days
SRHU18-508-428IR Hungary N-EU 2018	Maize DKC4717	1) 25 Apr 2018 2) - 3) 14 Sep 2018	61.591	359.3	17.14	14 Aug 2018	75	Kernels	<LOD	31	LOQ = 0.01 mg/kg Validated analytical method Max storage time: 159 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
<LOD = < 0.002 mg/kg

A 2.1.3.3 Wheat

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2016)	2	42 g a.s./ha	14	BBCH 51-79	28
Intended cGAP (24, 57-61*)	1	40 g a.s./ha	n.r.	BBCH 77	n.r.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.3.1 Study 1

Comments of zRMS:	The study has been accepted. Four trials were conducted to determine the amount of residue of acetamiprid in/on winter wheat at harvest. The field phase was performed at four field sites, 2 in Poland and 2 in Hungary. One application of the formulated product A-200SL-OR3-CPd (containing nominal concentration of acetamiprid 200 g/L) were made at a rate of 0.2 L/ha onto the crop under open field at BBCH 77. Specimens, grain and straw, were collected at normal commercial harvest. All samples were frozen and shipped frozen (<-18ºC) to the laboratory. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. No significant interference above 30 % of LOQ was detected in any of the reagent blanks or control specimen extracts for wheat matrices, so that a highly level of selectivity was demonstrated, and an additional confirmatory method is not necessary. Matrix effects on the detection of acetamiprid in extracts of wheat grain were lesser than 20% and thus considered insignificant, according to the guidelines. The calibration curves obtained for both ion mass transitions of Acetamiprid were linear with the coefficients of correlation (R) greater than 0.99. Linear regression was performed with 1/x weighting for wheat. The mean recovery values at the fortification levels of 0.01 mg/kg and 0.5 mg/kg or 1 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4. All precision values at the fortification levels of 0.01 mg/kg and 0.5 mg/kg or 1 mg/kg for both ion mass transitions were < 20%. The validated limit of quantification is 0.01 mg/kg in winter wheat. All treated samples of grain from each trial didn't present residues of acetamiprid after one application on treated plot (at BBCH 77). No acetamiprid residues were detected in any untreated winter wheat samples in this study. The method was successfully validated in winter wheat. Specificity, linearity, accuracy and precision of the method were fully demonstrated.

Reference:	KCA 6.3
Report	Determination of residues of acetamiprid in/on winter wheat under open field conditions following one applications of A-200SL-OR3-CPD in Northern Europe in 2019, M. Kurek-Molenda, 2020, 428SRPL9R02
Guideline(s):	Yes (OECD guideline 509, SANCO/825/00, SANCO/3029/99)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four new residue trials in wheat were conducted in the growing season 2019 in different localizations. The test item was wheat grain and straw samples (different varieties) treated with product A-200SL-OR3-CPd and control samples. The product was applied once at rate of 0.2 L/ha (corresponding to 40 g/ha of acetamiprid).
Specimens (grains and straw) were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Wheat samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 207 days. Results on residue trials in wheat are detailed summarised in Table A 6.
The residues of acetamiprid in wheat grains samples treated with A-200SL-OR3-CPd were below the limit of quantification, i.e. 0.01 mg/kg. Hence, they were below the maximum residue limits, i.e 0.1 mg/kg in wheat.

Detailed method validation is presented in section B5.

Table A 6: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
SRPL19-080-428IR Poland N-EU 2019	Wheat Ostroga	1) 10 Oct 2018 2) 15 Jun 2019 3) 05 Aug 2019	41.308	309.8	13.33	26.06.2019	77	Grain	<u><LOQ</u>	40	LOQ = 0.01 mg/kg Validated analytical method Max storage time: Grains: 170 days Straw: 172 days
								Straw	0.244		
SRPL19-081-428IR Poland N-EU 2019	Wheat Toras	1) 19 Sep 2018 2) 06 Jun 2019 3) 01 Aug 2019	40.202	301.7	13.33	11.06.2019	77	Grain	<LOQ	51	LOQ = 0.01 mg/kg Validated analytical method Max storage time: Grains: 174 days Straw: 176 days
								Straw	0.590		
SRHU19-589-428IR Hungary N-EU 2019	Wheat Pitbull	1) 15 Oct 2018 2) May 2019 3) 02 Jul 2019	30.029	292.7	10.26	12.06.2019	77	Grain	<LOQ	20	LOQ = 0.01 mg/kg Validated analytical method Max storage time: Grains: 204 days Straw: 206 days
								Straw	0.542		
SRHU19-590-428IR Hungary N-EU 2019	Wheat Solehio	1) 05 Nov 2018 2) May 2019 3) 01 Jul 2019	38.495	288.7	13.33	12.06.2019	77	Grain	<LOQ	19	LOQ = 0.01 mg/kg Validated analytical method Max storage time: Grains: 205 days Straw: 207 days
								Straw	0.546		

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
<LOD = < 0.002 mg/kg

A 2.1.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.1.7 Other/Special Studies

No new or additional studies have been submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.3.1)

A 3.1 TMDI calculations

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	98%	NL toddler	24,53	48%	Milk: Cattle	9%	Bananas	8%	Oranges	1%	7%
	57%	DE child	14,24	16%	Milk: Cattle	14%	Oranges	3%	Table grapes	0,5%	8%
	53%	NL child	13,19	20%	Milk: Cattle	5%	Oranges	3%	Bananas	0,8%	5%
	50%	FR child 3 15 yr	12,49	18%	Milk: Cattle	12%	Oranges	3%	Bovine: Muscle/meat	0,6%	3%
	48%	UK infant	11,90	31%	Milk: Cattle	5%	Oranges	2%	Bovine: Muscle/meat	0,5%	2%
	46%	FR toddler 2 3 yr	11,55	23%	Milk: Cattle	5%	Oranges	3%	Mandarins	0,5%	2%
	44%	ES child	11,02	10%	Milk: Cattle	9%	Olives for oil production	8%	Oranges	0,4%	3%
	38%	GEMS/Food G08	9,54	10%	Olives for oil production	4%	Milk: Cattle	4%	Swine: Muscle/meat	0,6%	4%
	37%	SE general	9,24	10%	Milk: Cattle	9%	Bovine: Muscle/meat	3%	Bananas	0,4%	2%
	37%	UK toddler	9,20	17%	Milk: Cattle	7%	Oranges	3%	Bovine: Muscle/meat	0,5%	2%
	37%	GEMS/Food G07	9,14	5%	Milk: Cattle	5%	Oranges	4%	Olives for oil production	0,6%	4%
	33%	GEMS/Food G10	8,13	5%	Olives for oil production	4%	Milk: Cattle	4%	Oranges	0,7%	3%
	32%	DE women 14-50 yr	8,02	10%	Milk: Cattle	7%	Oranges	2%	Swine: Muscle/meat	0,5%	3%
	31%	IE adult	7,68	4%	Oranges	3%	Milk: Cattle	3%	Grapefruits	0,5%	2%
	31%	GEMS/Food G11	7,65	6%	Milk: Cattle	3%	Olives for oil production	3%	Oranges	0,8%	3%
	31%	GEMS/Food G15	7,65	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Oranges	0,6%	5%
	30%	DE general	7,62	10%	Milk: Cattle	6%	Oranges	2%	Swine: Muscle/meat	0,5%	2%
	30%	GEMS/Food G06	7,52	4%	Olives for oil production	4%	Oranges	3%	Wheat	0,5%	6%
	28%	DK child	7,04	10%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	0,5%	3%
	27%	ES adult	6,86	5%	Olives for oil production	5%	Oranges	4%	Milk: Cattle	0,2%	2%
	27%	RO general	6,68	9%	Milk: Cattle	3%	Wine grapes	2%	Swine: Muscle/meat	0,4%	4%
	24%	NL general	5,98	7%	Milk: Cattle	4%	Oranges	2%	Swine: Muscle/meat	0,4%	2%
	22%	FR infant	5,51	13%	Milk: Cattle	1%	Beans (with pods)	0,9%	Oranges	0,2%	0,7%
	20%	FR adult	4,92	5%	Wine grapes	4%	Milk: Cattle	2%	Oranges	0,3%	2%
	17%	PT general	4,31	5%	Wine grapes	3%	Olives for oil production	2%	Oranges	0,3%	3%
	14%	DK adult	3,62	4%	Milk: Cattle	2%	Wine grapes	2%	Swine: Muscle/meat	0,2%	0,9%
	13%	UK vegetarian	3,26	3%	Oranges	3%	Milk: Cattle	2%	Wine grapes	0,2%	1%
	12%	UK adult	3,06	2%	Milk: Cattle	2%	Wine grapes	2%	Oranges	0,2%	0,9%
	12%	FI 3 yr	3,05	2%	Bananas	1%	Raspberries (red and yellow)	1%	Mandarins	0,4%	1%
	12%	IT toddler	3,00	3%	Wheat	2%	Lettuces	2%	Oranges	0,1%	4%
	11%	IT adult	2,66	2%	Lettuces	2%	Wheat	1%	Oranges	0,1%	3%
	10%	LT adult	2,38	3%	Milk: Cattle	2%	Swine: Muscle/meat	0,6%	Head cabbages	0,3%	1,0%
	9%	FI 6 yr	2,26	1%	Bananas	1%	Mandarins	1%	Raspberries (red and yellow)	0,3%	0,9%
	8%	FI adult	1,92	1%	Oranges	1%	Coffee beans	0,8%	Lettuces	1%	0,4%
	6%	IE child	1,43	3%	Milk: Cattle	0,5%	Wheat	0,3%	Swine: Muscle/meat	0,1%	0,6%
	4%	PL general	1,09	0,6%	Table grapes	0,6%	Head cabbages	0,5%	Cherries (sweet)	0,2%	1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Acetamiprid is unlikely to present a public health concern.

A 3.2 IEDI calculations

TMDI values do not exceed ADI therefore IEDI calculations are not required.

A 3.3 IESTI calculations - Raw commodities

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
79%	Quinces	0,8 / 0,8	20
76%	Peaches	0,2 / 0,2	19
73%	Cherries (sweet)	1,5 / 1,5	18
71%	Sweet peppers/bell	0,3 / 0,3	18
44%	Medlar	0,8 / 0,8	11
39%	Pears	0,4 / 0,07	9,8
31%	Apples	0,4 / 0,07	7,7
20%	Aubergines/egg plants	0,2 / 0,2	5,0
19%	Tomatoes	0,5 / 0,08	4,7
10%	Apricots	0,8 / 0,07	2,5
6%	Wheat	0,1 / 0,1	1,4
5%	Plums	0,03 / 0,03	1,3
2%	Rapeseeds/canola seeds	0,4 / 0,4	0,55
2%	Sweet corn	0,01 / 0,01	0,43
1%	Barley	0,05 / 0,05	0,28

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
60%	Cherries (sweet)	1,5 / 1,5	15
49%	Quinces	0,8 / 0,8	12
22%	Medlar	0,8 / 0,8	5,5
22%	Aubergines/egg plants	0,2 / 0,2	5,4
20%	Sweet peppers/bell peppers	0,3 / 0,3	4,9
15%	Peaches	0,2 / 0,2	3,7
9%	Pears	0,4 / 0,07	2,2
8%	Apples	0,4 / 0,07	2,0
5%	Tomatoes	0,5 / 0,08	1,3
3%	Wheat	0,1 / 0,1	0,84
3%	Apricots	0,8 / 0,07	0,77
2%	Plums	0,03 / 0,03	0,53
1,0%	Barley	0,05 / 0,05	0,24
0,8%	Rapeseeds/canola seeds	0,4 / 0,4	0,21
0,6%	Sweet corn	0,01 / 0,01	0,16

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
157%	Apricots	0,8 / 0,8	39
99%	Apples	0,4 / 0,4	25
95%	Pears	0,4 / 0,4	24
73%	Cherries (sweet)	1,5 / 1,5	18
61%	Tomatoes	0,5 / 0,5	15
47%	Quinces	0,8 / 0,8	12
43%	Peaches	0,2 / 0,2	11
33%	Medlar	0,8 / 0,8	8,1
31%	Sweet peppers/bell	0,3 / 0,3	7,7
12%	Aubergines/egg plants	0,2 / 0,2	3,0
6%	Wheat	0,1 / 0,1	1,4
3%	Plums	0,03 / 0,03	0,77
2%	Rapeseeds/canola seeds	0,4 / 0,4	0,55
1%	Barley	0,05 / 0,05	0,28
0,9%	Walnuts	0,07 / 0,07	0,24

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 1

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
60%	Cherries (sweet)	1,5 / 1,5	15
57%	Pears	0,4 / 0,4	14
48%	Apples	0,4 / 0,4	12
41%	Apricots	0,8 / 0,8	10
39%	Tomatoes	0,5 / 0,5	9,6
29%	Quinces	0,8 / 0,8	7,3
16%	Peaches	0,2 / 0,2	4,1
15%	Aubergines/egg plants	0,2 / 0,2	3,9
15%	Medlar	0,8 / 0,8	3,8
8%	Sweet peppers/bell peppers	0,3 / 0,3	2,1
5%	Plums	0,03 / 0,03	1,2
3%	Wheat	0,1 / 0,1	0,84
1,0%	Barley	0,05 / 0,05	0,24
0,8%	Rapeseeds/canola seeds	0,4 / 0,4	0,21
0,6%	Walnuts	0,07 / 0,07	0,15

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Peaches / canned	0,2 / 0,2	5,2	7%	Peaches / canned	0,2 / 0,2	1,6	87%	Apples / juice	0,4 / 0,4	22	53%	Apples / juice	0,4 / 0,4	13
13%	Peaches / juice	0,2 / 0,2	3,3	4%	Apples / juice	0,4 / 0,03	1,0	52%	Pears / juice	0,4 / 0,4	13	16%	Tomatoes / sauce/puree	0,5 / 0,5	4,1
10%	Quinces / jam	0,8 / 0,8	2,4	4%	Quinces / jam	0,8 / 0,8	1,0	38%	Tomatoes / juice	0,5 / 0,5	9,5	6%	Peaches / canned	0,2 / 0,2	1,6
7%	Apples / juice	0,4 / 0,03	1,7	2%	Wheat / bread/pizza	0,1 / 0,1	0,44	19%	Tomatoes / sauce/puree	0,5 / 0,5	4,8	4%	Quinces / jam	0,8 / 0,8	1,0
5%	Wheat / milling (flour)	0,1 / 0,1	1,2	2%	Wheat / pasta	0,1 / 0,1	0,38	15%	Peaches / canned	0,2 / 0,2	3,9	2%	Wheat / bread/pizza	0,1 / 0,1	0,44
4%	Pears / juice	0,4 / 0,03	1,0	1%	Barley / beer	0,05 / 0,01	0,36	13%	Peaches / juice	0,2 / 0,2	3,3	2%	Wheat / pasta	0,1 / 0,1	0,38
2%	Wheat / milling (wholemeal)-	0,1 / 0,1	0,55	1%	Wheat / bread (wholemeal)	0,1 / 0,1	0,35	10%	Quinces / jam	0,8 / 0,8	2,4	1%	Barley / beer	0,05 / 0,01	0,36
2%	Tomatoes / juice	0,5 / 0,02	0,42	0,7%	Tomatoes / sauce/puree	0,5 / 0,02	0,18	5%	Wheat / milling (flour)	0,1 / 0,1	1,2	1%	Wheat / bread (wholemeal)	0,1 / 0,1	0,35
1%	Plums / juice	0,03 / 0,03	0,28	0,5%	Maize / oil	0,01 / 0,25	0,13	2%	Wheat / milling (wholemeal)-	0,1 / 0,1	0,55	0,5%	Maize / oil	0,01 / 0,25	0,13
0,9%	Rapeseeds / oils	0,4 / 0,8	0,24	0,09%	Millet / boiled	0,01 / 0	0,02	1%	Plums / juice	0,03 / 0,03	0,28	0,09%	Millet / boiled	0,01 / 0	0,02
0,9%	Maize / oil	0,01 / 0,25	0,23	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,9%	Rapeseeds / oils	0,4 / 0,8	0,24	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,8%	Tomatoes / sauce/puree	0,5 / 0,02	0,21	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,9%	Maize / oil	0,01 / 0,25	0,23	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,7%	Barley / cooked	0,05 / 0,05	0,18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,7%	Barley / cooked	0,05 / 0,05	0,18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,4%	Barley / milling (flour)	0,05 / 0,05	0,09	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,4%	Barley / milling (flour)	0,05 / 0,05	0,09	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,2%	Millet / boiled	0,01 / 0	0,05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,2%	Millet / boiled	0,01 / 0	0,05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Acetamiprid is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.5 NESTI calculations

NESTI calculations are not required

A 3.6 NTMDI calculations

NTMDI calculations are not required

Appendix 4 Additional information provided by the applicant

No additional information has been provided.